Nos. 25-1611, 25-1612

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; NICOLE MAPHIS,

Plaintiffs-Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in the official capacity as Secretary of the United States Department of Health & Human Services,

Defendants-Appellants.

COMMONWEALTH OF MASSACHUSETTS; STATE OF CALIFORNIA; STATE OF MARYLAND; STATE OF WASHINGTON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF DELAWARE; STATE OF HAWAII; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF WISCONSIN,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., in the official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; NATIONAL CANCER INSTITUTE; NATIONAL EYE INSTITUTE; NATIONAL HEART LUNG AND BLOOD INSTITUTE; NATIONAL HUMAN GENOME RESEARCH INSTITUTE; NATIONAL INSTITUTE ON AGING; NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM; NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING; EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION

DISORDERS; NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH; NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; NATIONAL INSTITUTE OF MENTAL HEALTH; NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES; NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE; NATIONAL INSTITUTE OF NURSING RESEARCH; NATIONAL LIBRARY OF MEDICINE; NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES; JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES; NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH; NIH CENTER FOR SCIENTIFIC REVIEW,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Massachusetts

APPENDIX - VOLUME I

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US District Court Docket

United States District Court, Massachusetts

(Boston)

This case was retrieved on 09/24/2025

Header

Case Number: 1:25cv10787
Date Filed: 04/02/2025
Assigned To: Judge William G. Young
Nature of Suit: Other Statutes - Administrative Procedure Act/Review or Appeal of Agency Decision (899)
Cause: Administrative Procedure Act
Lead Docket: None
Other Docket: 1:25cv10814, USCA - First Circuit, 25-01611
Jurisdiction: U.S. Government Defendant

Class Code: Open
Statute: 05:702
Jury Demand: None
Demand Amount: $0
NOS Description: Other Statutes - Administrative Procedure Act/Review or Appeal of Agency Decision

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Proceedings

#	Date	Proceeding Text	Source
1	04/02/2025	COMPLAINT For Declaratory and Injunctive Relief against All Defendants Filing fee: $ 405, receipt number AMADC-10928559 (Fee Status: Filing Fee paid), filed by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Civil Cover Sheet Exhibit A, # 2 Category Form Exhibit B)(Rossman, Jessie) Modified on 4/2/2025 to modify docket text (CEH). (Main Document 1 replaced on 4/4/2025) (MBM). (Entered: 04/02/2025)	
2	04/02/2025	ELECTRONIC NOTICE of Case Assignment. District Judge Patti B. Saris assigned to case. If the trial Judge issues an Order of Reference of any matter in this case to a Magistrate Judge, the matter will be transmitted to Magistrate Judge M. Page Kelley. (JKK) (Entered: 04/02/2025)	
3	04/02/2025	Summons Issued as to Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services. Counsel receiving this notice electronically should download this summons, complete one for each defendant and serve it in accordance with Fed.R.Civ.P. 4 and LR 4.1. Summons will be mailed to plaintiff(s) not receiving notice electronically for completion of service. (CEH) (Entered: 04/02/2025)	
4	04/02/2025	NOTICE of Appearance by Suzanne Schlossberg on behalf of American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis (Schlossberg, Suzanne) (Entered: 04/02/2025)	

#	Date	Proceeding Text	Source
5	04/02/2025	District Judge Patti B. Saris: ENDORSED ORDER entered re 1 Complaint for Declaratory and Injunctive Relief against All Defendants filed by American Public Health Association, Nicole Maphis, United Auto Workers, Peter Lurie, Brittany Charlton, Ibis Reproductive Health, Katie Edwards. "Pursuant to U.S. C. 455(a), I recuse myself on the ground my impartiality might reasonably be questioned." (CGK) (Entered: 04/02/2025)	
6	04/02/2025	District Judge Patti B. Saris: ORDER entered. ORDER OF RECUSAL. Pursuant to 28 U.S.C. 455(a), I recuse myself on the ground that my impartiality might reasonably be questioned and direct the clerk forthwith to reassign the case randomly to another District Judge.(CGK) (Entered: 04/02/2025)	
7	04/02/2025	ELECTRONIC NOTICE of Case Reassignment. Judge Brian E. Murphy assigned to case. (RN) (Entered: 04/02/2025)	
8	04/07/2025	NOTICE of Appearance by Anuj K. Khetarpal on behalf of United States Department of Health and Human Services, Robert F. Kennedy, Jr., National Institutes of Health, Jay Bhattacharya (Khetarpal, Anuj) (Entered: 04/07/2025)	
9	04/10/2025	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Olga Akselrod Filing fee: $ 125, receipt number AMADC-10945811 by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 04/10/2025)	
10	04/10/2025	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Alexis Agathocleous Filing fee: $ 125, receipt number AMADC-10945813 by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 04/10/2025)	
11	04/10/2025	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Shalini Goel Agarwal Filing fee: $ 125, receipt number AMADC-10945817 by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 04/10/2025)	
12	04/10/2025	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Michel-Ange Desruisseaux Filing fee: $ 125, receipt number AMADC-10945818 by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 04/10/2025)	
13	04/10/2025	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Oscar Heanue Filing fee: $ 125, receipt number AMADC-10945822 by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 04/10/2025)	
14	04/10/2025	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Lisa S. Mankofsky Filing fee: $ 125, receipt number AMADC-10945823 by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered:	

#	Date	Proceeding Text	Source
		04/10/2025)	
15	04/10/2025	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Rachel Meeropol Filing fee: $ 125, receipt number AMADC-10945828 by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 04/10/2025)	
16	04/10/2025	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Alejandro Ortiz Filing fee: $ 125, receipt number AMADC-10945830 by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 04/10/2025)	
17	04/11/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 9 Motion for Leave to Appear Pro Hac Vice Added Olga Akselrod. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/11/2025)	
18	04/11/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 10 Motion for Leave to Appear Pro Hac Vice Added Alexis Agathocleous. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/11/2025)	
19	04/11/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 11 Motion for Leave to Appear Pro Hac Vice Added Shalini Goel Agarwal. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/11/2025)	
20	04/11/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 12 Motion for Leave to Appear Pro Hac Vice Added Michel-Ange Desruisseaux. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the	

#	Date	Proceeding Text	Source
		docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/11/2025)	
21	04/11/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 13 Motion for Leave to Appear Pro Hac Vice Added Oscar Heanue. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/11/2025)	
22	04/11/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 14 Motion for Leave to Appear Pro Hac Vice Added Lisa S. Mankofsky. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/11/2025)	
23	04/11/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 15 Motion for Leave to Appear Pro Hac Vice Added Rachel Meeropol. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/11/2025)	
24	04/11/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 16 Motion for Leave to Appear Pro Hac Vice Added Alejandro Ortiz. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/11/2025)	
25	04/14/2025	NOTICE of Appearance by Alexis Agathocleous on behalf of American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter	

#	Date	Proceeding Text	Source
		Lurie, Nicole Maphis (Agathocleous, Alexis) (Entered: 04/14/2025)	
26	04/14/2025	NOTICE of Appearance by Olga Akselrod on behalf of American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis (Akselrod, Olga) (Entered: 04/14/2025)	
27	04/14/2025	NOTICE of Appearance by Rachel Anne Meeropol on behalf of American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis (Meeropol, Rachel) (Entered: 04/14/2025)	
28	04/14/2025	MOTION for Leave to File Excess Pages by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis.(Schlossberg, Suzanne) (Entered: 04/14/2025)	
29	04/14/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 28 Motion for Leave to File Excess Pages ; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (MBM) (Entered: 04/14/2025)	
30	04/15/2025	NOTICE of Appearance by Oscar Heanue on behalf of American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis (Heanue, Oscar) (Entered: 04/15/2025)	
31	04/16/2025	NOTICE of Appearance by Alejandro Ortiz on behalf of American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis (Ortiz, Alejandro) (Entered: 04/16/2025)	
32	04/16/2025	NOTICE of Appearance by Lisa Mankofsky on behalf of American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis (Mankofsky, Lisa) (Entered: 04/16/2025)	
33	04/23/2025	MOTION to Seal by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis.(Schlossberg, Suzanne) (Entered: 04/23/2025)	
34	04/23/2025	MEMORANDUM in Support re 33 MOTION to Seal filed by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Schlossberg, Suzanne) (Entered: 04/23/2025)	
35	04/24/2025	NOTICE of Appearance by Shalini Goel Agarwal on behalf of American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis (Agarwal, Shalini) (Entered: 04/24/2025)	
36	04/24/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 33 Motion to Seal. Counsel will receive an email within twenty-four (24) hours of this order with instructions for submitting sealed documents for which leave has been granted in accordance with the Local Rules of the U.S. District Court of Massachusetts. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (MBM) (Entered: 04/24/2025)	
37	04/25/2025	MOTION for Preliminary Injunction by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit A-Proposed Order)(Rossman, Jessie) (Entered: 04/25/2025)	
38	04/25/2025	DECLARATION re 37 MOTION for Preliminary Injunction by American Public Health Association, Ibis Reproductive Health,	

#	Date	Proceeding Text	Source
		United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6, # 7 Exhibit 7, # 8 Exhibit 8, # 9 Exhibit 9, # 10 Exhibit 10, # 11 Exhibit 11, # 12 Exhibit 12, # 13 Exhibit 13, # 14 Exhibit 14, # 15 Exhibit 15, # 16 Exhibit 16, # 17 Exhibit 17, # 18 Exhibit 18, # 19 Exhibit 19, # 20 Exhibit 20, # 21 Exhibit 21, # 22 Exhibit 22, # 23 Exhibit 23, # 24 Exhibit 24, # 25 Exhibit 25, # 26 Exhibit 26, # 27 Exhibit 27, # 28 Exhibit 28, # 29 Exhibit 29, # 30 Exhibit 30, # 31 Exhibit 31, # 32 Exhibit 32, # 33 Exhibit 33, # 34 Exhibit 34, # 35 Exhibit 35, # 36 Exhibit 36, # 37 Exhibit 37, # 38 Exhibit 38, # 39 Exhibit 39, # 40 Exhibit 40, # 41 Exhibit 41, # 42 Exhibit 42)(Rossman, Jessie) (Additional attachment(s) added on 5/7/2025: # 43 Sealed - Exhibit 19, # 44 Sealed - Exhibit 23, # 45 Sealed - Exhibit 24, # 46 Sealed - Exhibit 28, # 47 Sealed - Exhibit 29, # 48 Sealed - Exhibit 32, # 49 Sealed - Exhibit 35, # 50 Sealed - Exhibit 36, # 51 Sealed - Exhibit 37, # 52 Sealed - Exhibit 38, # 53 Sealed - Exhibit 39, # 54 Sealed - Exhibit 42) (MAP). (Entered: 04/25/2025)	
39	04/25/2025	MOTION for Protective Order Regarding Certain Organizational Declarants by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Attachments: # 1 Exhibit A-Proposed Order)(Rossman, Jessie) (Entered: 04/25/2025)	
40	04/25/2025	MEMORANDUM in Support re 39 MOTION for Protective Order Regarding Certain Organizational Declarants filed by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Rossman, Jessie) (Entered: 04/25/2025)	
41	04/25/2025	MEMORANDUM in Support re 37 MOTION for Preliminary Injunction filed by American Public Health Association, Ibis Reproductive Health, United Auto Workers, Brittany Charlton, Katie Edwards, Peter Lurie, Nicole Maphis. (Rossman, Jessie) (Entered: 04/25/2025)	
42	04/28/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered. Defendants are ordered to respond to the Motion for Protective Order (Dkt. 39) by 5 p.m. on May 5, 2025.(MBM) (Entered: 04/28/2025)	
43	04/28/2025	Amicus Curiae APPEARANCE entered by Amish Aajay Shah on behalf of Association of American Medical Colleges, American Association of State Colleges and Universities, American Council on Education, Association of American Universities, Association of Governing Boards of Universities and Colleges, Association of Public and Land-grant Universities, COGR, National Association of Independent Colleges and Universities. (Shah, Amish) (Entered: 04/28/2025)	
44	04/28/2025	Amicus Curiae APPEARANCE entered by Douglas Hallward-Driemeier on behalf of American Association of State Colleges and Universities, American Council on Education, Association of American Medical Colleges, Association of American Universities, Association of Governing Boards of Universities and Colleges, Association of Public and Land-grant Universities, COGR, National Association of Independent Colleges and Universities. (Hallward-Driemeier, Douglas) (Entered: 04/28/2025)	
45	04/28/2025	Amicus Curiae APPEARANCE entered by John P. Bueker on behalf of American Association of State Colleges and Universities, American Council on Education, Association of American Medical Colleges, Association of American Universities, Association of Governing Boards of Universities and Colleges, Association of Public and Land-grant Universities, COGR, National Association	

#	Date	Proceeding Text	Source
		of Independent Colleges and Universities. (Bueker, John) (Entered: 04/28/2025)	
46	04/28/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Stephanie A. Webster Filing fee: $ 125, receipt number AMADC-10976480 by American Association of State Colleges and Universities, American Council on Education, Association of American Medical Colleges, Association of American Universities, Association of Governing Boards of Universities and Colleges, Association of Public and Land-grant Universities, COGR, National Association of Independent Colleges and Universities.(Bueker, John) (Additional attachment(s) added on 4/29/2025: # 1 Certificate of Stephanie A. Webster) (MBM). (Entered: 04/28/2025)	
47	04/28/2025	MOTION for Leave to File AMICUS CURIAE BRIEF (Unopposed) by American Association of State Colleges and Universities, American Council on Education, Association of American Medical Colleges, Association of American Universities, Association of Governing Boards of Universities and Colleges, Association of Public and Land-grant Universities, COGR, National Association of Independent Colleges and Universities. (Attachments: # 1 Proposed AMICUS CURIAE BRIEF)(Bueker, John) (Entered: 04/28/2025)	
48	04/29/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 46 Motion for Leave to Appear Pro Hac Vice Added Stephanie A. Webster. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MBM) (Entered: 04/29/2025)	
49	04/29/2025	Amicus Curiae APPEARANCE entered by Stephanie A. Webster on behalf of American Association of State Colleges and Universities, American Council on Education, Association of American Medical Colleges, Association of American Universities, Association of Governing Boards of Universities and Colleges, Association of Public and Land-grant Universities, National Association of Independent Colleges and Universities. (Webster, Stephanie) (Entered: 04/29/2025)	
50	04/29/2025	NOTICE of Appearance by Michel-Ange Desruisseaux on behalf of Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers (Desruisseaux, Michel-Ange) (Entered: 04/29/2025)	
51	05/01/2025	Judge Brian E. Murphy: ELECTRONIC ORDER OF RECUSAL - In accordance with 28 U.S.C. 455(a), I hereby recuse myself from this proceeding. The Clerk is directed to return the case for reassignment.Associated Cases: 1:25-cv-10814-BEM, 1:25-cv-10787-BEM(BIB) (Entered: 05/01/2025)	
52	05/01/2025	ELECTRONIC NOTICE of Reassignment. Judge William G. Young added. Judge Brian E. Murphy no longer assigned to case. (CM) (Entered: 05/01/2025)	
53	05/02/2025	Amicus Curiae APPEARANCE by Megan Barbero on behalf of American Society for Biochemistry and Molecular Biology, American Society for Cell Biology, American Society for Microbiology, Federation of American Societies for Experimental Biology, American Institute of Biological Sciences, American Sociological Association, Association for Women in Science,	

#	Date	Proceeding Text	Source
		Ecological Society of America, Gerontological Society of America, Infectious Diseases Society of America, Society of Environmental Toxicology and Chemistry of North America (Barbero, Megan) Modified on 5/2/2025to Correct Filing Event as Counsel Filed Their Appearance Under the Wrong Event in CM/ECF (MAP). (Entered: 05/02/2025)	
54	05/02/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Dismas Locaria Filing fee: $ 125, receipt number AMADC-10985379 by American Institute of Biological Sciences, American Society for Biochemistry and Molecular Biology, American Society for Cell Biology, American Society for Microbiology, American Sociological Association, Association for Women in Science, Ecological Society of America, Federation of American Societies for Experimental Biology, Gerontological Society of America, Infectious Diseases Society of America, Society of Environmental Toxicology and Chemistry of North America. (Attachments: # 1 Exhibit A - Certification of Dismas Locaria)(Barbero, Megan) (Entered: 05/02/2025)	
55	05/02/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Kyle H. Keraga Filing fee: $ 125, receipt number AMADC-10985410 by American Institute of Biological Sciences, American Society for Biochemistry and Molecular Biology, American Society for Cell Biology, American Society for Microbiology, American Sociological Association, Association for Women in Science, Ecological Society of America, Federation of American Societies for Experimental Biology, Gerontological Society of America, Infectious Diseases Society of America, Society of Environmental Toxicology and Chemistry of North America. (Attachments: # 1 Exhibit A - Certification of Kyle H. Keraga)(Barbero, Megan) (Entered: 05/02/2025)	
56	05/02/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Emily R. Marcy Filing fee: $ 125, receipt number AMADC-10985426 by American Institute of Biological Sciences, American Society for Biochemistry and Molecular Biology, American Society for Cell Biology, American Society for Microbiology, American Sociological Association, Association for Women in Science, Ecological Society of America, Federation of American Societies for Experimental Biology, Gerontological Society of America, Infectious Diseases Society of America, Society of Environmental Toxicology and Chemistry of North America. (Attachments: # 1 Exhibit A - Certification of Emily R. Marcy)(Barbero, Megan) (Entered: 05/02/2025)	
57	05/02/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 54 Motion for Leave to Appear Pro Hac Vice Added Dismas Locaria. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. Amicus Curiae APPEARANCE must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 05/02/2025)	
58	05/02/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 55 Motion for Leave to Appear Pro Hac Vice Added Kyle H. Keraga. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-	

#	Date	Proceeding Text	Source
		account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. Amicus Curiae APPEARANCE must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 05/02/2025)	
59	05/02/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 56 Motion for Leave to Appear Pro Hac Vice Added Emily R. Marcy. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. Amicus Curiae APPEARANCE must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 05/02/2025)	
60	05/02/2025	MOTION for Leave to File AMICUS CURIAE BRIEF by American Institute of Biological Sciences, American Society for Biochemistry and Molecular Biology, American Society for Cell Biology, American Society for Microbiology, American Sociological Association, Association for Women in Science, Ecological Society of America, Federation of American Societies for Experimental Biology, Gerontological Society of America, Infectious Diseases Society of America, Society of Environmental Toxicology and Chemistry of North America. (Attachments: # 1 Exhibit Proposed Amicus Curiae Brief)(Barbero, Megan) (Entered: 05/02/2025)	
61	05/02/2025	Assented to MOTION for Protective Order and Joint Motion for Briefing Schedule by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Exhibit Agreed Proposed Protective Order)(Rossman, Jessie) (Entered: 05/02/2025)	
62	05/05/2025	Judge William G. Young: ELECTRONIC ORDER entered allowed 61 Assented to MOTION for Protective Order and Joint Motion for Briefing Schedule. (Entered: 05/06/2025)	
63	05/05/2025	Judge William G. Young ORDER entered: PROTECTIVE ORDER Regarding Certain Organizational Declarants. (MAP) (Entered: 05/06/2025)	
64	05/06/2025	ELECTRONIC NOTICE Setting Hearing on Motion 37 MOTION for Preliminary Injunction : Motion Hearing set for 5/22/2025 11:00 AM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here.(KB) (Entered: 05/06/2025)	
65	05/07/2025	AFFIDAVIT OF SERVICE Executed by Nicole Maphis, Ibis Reproductive Health, American Public Health Association, Peter Lurie, United Auto Workers, Brittany Charlton, Katie Edwards. All Defendants. Acknowledgement filed by Nicole Maphis, Ibis Reproductive Health, American Public Health Association, Peter Lurie, United Auto Workers, Brittany Charlton, Katie Edwards. (Attachments: # 1 Exhibit A-National Institutes of Health, # 2 Exhibit B-Jay Bhattacharya, # 3 Exhibit C-U.S. Dept. of Health and Human Services, # 4 Exhibit D-Robert F. Kennedy Jr., # 5 Exhibit	

#	Date	Proceeding Text	Source
		E-U.S. Attorney General, # 6 Exhibit F-U.S. Attorney, District of MA)(Schlossberg, Suzanne) (Entered: 05/07/2025)	
66	05/12/2025	Opposition re 37 MOTION for Preliminary Injunction filed by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services. (Attachments: # 1 Lorsch Declaration, # 2 Exhibit A, # 3 Exhibit B)(Khetarpal, Anuj) (Entered: 05/12/2025)	
67	05/13/2025	Amicus Curiae APPEARANCE entered by Dismas Locaria on behalf of American Institute of Biological Sciences, American Society for Biochemistry and Molecular Biology, American Society for Cell Biology, American Society for Microbiology, American Sociological Association, Association for Women in Science, Ecological Society of America, Federation of American Societies for Experimental Biology, Gerontological Society of America, Infectious Diseases Society of America, Society of Environmental Toxicology and Chemistry of North America (Locaria, Dismas) Modified on 5/13/2025 to Correct Docket as Counsel Filed the Appearance Under the Wrong Event in CM/ECF. (MAP). (Entered: 05/13/2025)	
68	05/13/2025	Amicus Curiae APPEARANCE entered by Kyle Keraga on behalf of American Institute of Biological Sciences, American Society for Biochemistry and Molecular Biology, American Society for Cell Biology, American Society for Microbiology, American Sociological Association, Association for Women in Science, Ecological Society of America, Federation of American Societies for Experimental Biology, Gerontological Society of America, Infectious Diseases Society of America, Society of Environmental Toxicology and Chemistry of North America (Keraga, Kyle) Modified on 5/13/2025 to Correct Docket as Counsel Filed the Appearance Under the Wrong Event in CM/ECF. (MAP). (Entered: 05/13/2025)	
69	05/13/2025	Amicus Curiae APPEARANCE entered by Emily Rose Marcy on behalf of American Institute of Biological Sciences, American Society for Biochemistry and Molecular Biology, American Society for Cell Biology, American Society for Microbiology, American Sociological Association, Association for Women in Science, Ecological Society of America, Federation of American Societies for Experimental Biology, Gerontological Society of America, Infectious Diseases Society of America, Society of Environmental Toxicology and Chemistry of North America (Marcy, Emily) Modified on 5/13/2025 to Correct Docket as Counsel Filed the Appearance Under the Wrong Event in CM/ECF. (MAP). (Entered: 05/13/2025)	
70	05/16/2025	STATUS REPORT Joint Status Report by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Schlossberg, Suzanne) (Entered: 05/16/2025)	
71	05/19/2025	REPLY to Response to 37 MOTION for Preliminary Injunction filed by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Agarwal, Shalini) (Entered: 05/19/2025)	
72	05/19/2025	DECLARATION re 71 Reply to Response to Motion, by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Exhibit 43 - NIH Contracts webpage, # 2 Exhibit 44 - 2/21/25 Directive on NIH Priorities, # 3 Exhibit 45 - S Delaney Suppl Decl, # 4 Exhibit 46 - J Berg Suppl Decl, # 5 Exhibit 47 - 3/31/25 Kirschstein NRSA NOFO, # 6 Exhibit 48 - 1/22/25 Kirschstein NRSA NOFO, # 7 Exhibit 49 - Updates to NIH Institutional Training Grant Applications webpage, # 8 Exhibit 50 -	

#	Date	Proceeding Text	Source
		3/11/25 Memo re: NIH's Initial Actions re EOs, # 9 Exhibit 51 - NIH Research General Terms and Conditions, # 10 Exhibit 52 - N Maphis Suppl Decl, # 11 Exhibit 53 - Mallapty Nature article, # 12 Exhibit 54 - K Edwards Suppl Decl)(Agarwal, Shalini) (Entered: 05/19/2025)	
73	05/20/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Kenneth Parreno Filing fee: $ 125, receipt number AMADC-11019317 by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Exhibit A-Certificate)(Rossman, Jessie) (Entered: 05/20/2025)	
74	05/20/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 73 Motion for Leave to Appear Pro Hac Vice Added Kenneth Parreno. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MAP) (Entered: 05/20/2025)	
75	05/22/2025	Judge William G. Young ELECTRONIC ORDER entered: allowed 47 MOTION for Leave to File Amici Curiae Brief ; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (MAP) (Entered: 05/22/2025)	
76	05/22/2025	AMICUS BRIEF filed by American Association of State Colleges and Universities, American Council on Education, American Institute of Biological Sciences, Association of American Medical Colleges, Association of American Universities, Association of Governing Boards of Universities and Colleges, Association of Public and Land-grant Universities, National Association of Independent Colleges and Universities . (Bueker, John) (Entered: 05/22/2025)	
77	05/22/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Motion Hearing held on 5/22/2025 re 37 MOTION for Preliminary Injunction filed by American Public Health Association, Nicole Maphis, United Auto Workers, Peter Lurie, Brittany Charlton, Ibis Reproductive Health, Katie Edwards. The motion is collapsed with trial on the merits in accordance with Rule 65(a). The parties agree to treat defendants' opposition as a motion to dismiss and wish to proceed with argument today. Court stands on its order on subject matter jurisdiction entered in related case 1:25-cv-10814-WGY. Court hears argument on the opposition treated as a motion to dismiss. Court takes the matter under advisement. Plaintiffs to provide spreadsheet of grants. Defendants to produce administrative records as to directives. The Court will hold a status conference in this case and the related case to coordinate case management. (Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Kenneth Parreno, Shalini Goel Agarwal, Jessie Rossman, Lisa Mankofsky, Olga Akselrod for plaintiffs and Anuj Khetarpal for defendants) (KB) (Entered: 05/23/2025)	
78	05/23/2025	ELECTRONIC NOTICE of Hearing. Status Conference re case management of related cases set for 6/3/2025 11:00 AM in Courtroom 18 (In person only) before Judge William G. Young. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access	

#	Date	Proceeding Text	Source
		to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here.Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 05/23/2025)	
79	05/23/2025	MEMORANDUM OF LAW by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers to 41 Memorandum in Support of Motion,. (Agarwal, Shalini) (Entered: 05/23/2025)	
80	05/27/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 60 Motion for Leave to File Amici Curiae Brief ; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (KB) (Entered: 05/27/2025)	
81	05/27/2025	AMICUS BRIEF filed by American Institute of Biological Sciences, American Society for Biochemistry and Molecular Biology, American Society for Cell Biology, American Society for Microbiology, American Sociological Association, Association for Women in Science, Ecological Society of America, Federation of American Societies for Experimental Biology, Gerontological Society of America, Infectious Diseases Society of America, Society of Environmental Toxicology and Chemistry of North America in Support of Plaintiffs' Motion for Preliminary Injunction. (Barbero, Megan) (Entered: 05/27/2025)	
82	05/30/2025	Transcript of Status Conference/Motion to Dismiss Hearing held on May 22, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 6/20/2025. Redacted Transcript Deadline set for 6/30/2025. Release of Transcript Restriction set for 8/28/2025. (DRK) (Entered: 05/30/2025)	
83	05/30/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm (DRK) (Entered: 05/30/2025)	
84	05/30/2025	Judge William G. Young: ORDER entered: MEMORANDUM AND ORDER: The Motion to Dismiss, ECF No. 66 is ALLOWED in Part as to Counts IV, VI, and VII, Which Are Dismissed Without Prejudice, and DENIED In Part as to The Remaining Counts. (Sonnenberg, Elizabeth) (Entered: 05/30/2025)	
85	06/02/2025	Notice of Production of Administrative Record by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services (Attachments: # 1 Certification of Administrative Record)(Khetarpal, Anuj) (Entered: 06/02/2025)	
86	06/03/2025	Amended Notice of Production of Administrative Record by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services (Attachments: # 1 Certification of Administrative Record)(Khetarpal, Anuj) Modified on 6/4/2025 (MAP). (Entered:	

#	Date	Proceeding Text	Source
		06/03/2025)	
87	06/03/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Status Conference held on 6/3/2025. Government has produced administrative record in both cases. The Court hears from parties in both cases regarding schedule and June 16th hearing. Court will hear argument on Phase 1 from 10am-1pm on June 16th in both cases. The Court adopts the proposed schedule filed in 25-cv-10814 Document 113 at page 2. The Court modifies the proposed schedule at page 4 as follows: By June 20, 2025, defendants may move to dismiss plaintiffs' claims related to alleged reasonable delay. By July 9, 2025, defendants must lodge the administrative record. Court and parties discuss phase II. Record to be supplemented as to the challenged directives as directed by the Court. If the case(s) were to resolve the parties shall inform the Clerk. (Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Kenneth Parreno, Jessie Rossman, Olga Akselrod, Suzanne Schlossberg, Gerard Cedrone, Katherine Dirks, Phoebe Lockhart for plaintiffs and Anuj Khetarpal and Thomas Ports, Jr. for defendants) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/04/2025)	
88	06/04/2025	ELECTRONIC NOTICE of Hearing. Oral argument on Phase I set for 6/16/2025 10:00 AM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here.(KB) (Entered: 06/04/2025)	
89	06/05/2025	Transcript of Status Conference held on June 3, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 6/26/2025. Redacted Transcript Deadline set for 7/7/2025. Release of Transcript Restriction set for 9/3/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 06/05/2025)	
90	06/05/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(DRK) (Entered: 06/05/2025)	
91	06/05/2025	STIPULATION Regarding Phase One Schedule Modifications by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Rossman, Jessie) (Entered: 06/05/2025)	
92	06/06/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Ilann Maazel Filing fee: $ 125, receipt number AMADC-11054656 by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 06/06/2025)	
93	06/06/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Matthew Brinckerhoff Filing fee: $ 125, receipt number AMADC-	

#	Date	Proceeding Text	Source
		11054673 by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 06/06/2025)	
94	06/06/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Max Selver Filing fee: $ 125, receipt number AMADC-11054681 by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 06/06/2025)	
95	06/06/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Sydney Zazzaro Filing fee: $ 125, receipt number AMADC-11054705 by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 06/06/2025)	
96	06/09/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 92 Motion for Leave to Appear Pro Hac Vice Added Ilann Maazel. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 06/09/2025)	
97	06/09/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 93 Motion for Leave to Appear Pro Hac Vice Added Matthew Brinckerhoff. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MAP) (Entered: 06/09/2025)	
98	06/09/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 94 Motion for Leave to Appear Pro Hac Vice Added Max Selver. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 06/09/2025)	
99	06/09/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 95 Motion for Leave to Appear Pro Hac Vice Added Sydney Zazzaro. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions	

#	Date	Proceeding Text	Source
		https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 06/09/2025)	
100	06/09/2025	NOTICE of Appearance by Matthew Brinckerhoff on behalf of Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers (Brinckerhoff, Matthew) (Entered: 06/09/2025)	
101	06/09/2025	TRIAL BRIEF Defendants' Merits Brief Concerning Phase 1 Claims by All Defendants. (Khetarpal, Anuj) (Entered: 06/09/2025)	
102	06/09/2025	MOTION Complete the Administrative Record by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Supplement Plaintiffs' Memorandum of Law in Support of Motion to Complete the Administrative Record, # 2 Affidavit of Matthew D. Brinckerhoff, Esq., # 3 Exhibit 1 - Letter, dated June 5, 2025, # 4 Exhibit 2 - Email Exchange Between Jessie Rossman and Anuj Khetarpal)(Brinckerhoff, Matthew) (Entered: 06/09/2025)	
103	06/09/2025	PRETRIAL MEMORANDUM by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Exhibit A - Proposed Order, # 2 Affidavit of Matthew D. Brinckerhoff, Esq., # 3 Exhibit 55 - Scott Delaney Second Supplemental Declaration, # 4 Exhibit 56 - Katie Edwards Second Supplemental Declaration)(Brinckerhoff, Matthew) (Entered: 06/09/2025)	
104	06/10/2025	APHA Plaintiffs' Exhibit List and Witness List for Phase 1 Proceeding by All Plaintiffs.. (Schlossberg, Suzanne) (Entered: 06/10/2025)	
105	06/11/2025	ELECTRONIC NOTICE of Hearing. Final Pretrial Conference set for 6/12/2025 11:00 AM in Courtroom 18 (Remote only) before Judge William G. Young. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/11/2025)	
106	06/11/2025	NOTICE of Appearance by Max Roller Selver on behalf of Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers (Selver, Max) (Entered: 06/11/2025)	
107	06/11/2025	NOTICE of Appearance by Sydney Kathryn Zazzaro on behalf of Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers (Zazzaro, Sydney) (Entered: 06/11/2025)	
108	06/11/2025	Certification of the Administrative Record (Updated) by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services re 86 Notice (Other), (Attachments: # 1 Email, # 2 Certification, # 3 Ex A to certification, # 4 Ex B to certification, # 5 Ex C to certification, # 6 NIH_GRANTS_003825-3910, # 7 NIH_GRANTS_003911-3995, # 8 NIH_GRANTS_003996-4081, # 9 NIH_GRANTS_004082-4165, # 10 NIH_GRANTS_004166-4251, # 11 NIH_GRANTS_004252, # 12 NIH_GRANTS_004253-54, # 13 NIH_GRANTS_004255-57, # 14 NIH_GRANTS_004258-69, # 15 NIH_GRANTS_004270)(Khetarpal, Anuj) Modified on 6/12/2025 (MAP). (Entered: 06/11/2025)	
109	06/12/2025	Opposition re 102 MOTION Complete the Administrative Record filed by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services. (Attachments: # 1 Exhibit Exhibit A)(Khetarpal, Anuj) (Entered: 06/12/2025)	

#	Date	Proceeding Text	Source
110	06/12/2025	Judge William G. Young: ELECTRONIC ORDER entered re 102 Motion MOTION Complete the Administrative Record by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. Motion allowed in part and denied in part as follows: A. Grants not terminated- Denied as moot B. Termination forms- Allowed. "Guidance" is not "deliberation." C. HHS and DOGE imput: Denied on the representation that such search has been made. D. AI Use: Allowed. E. Metadata: Denied without prejudice to seeking such discovery beyond the APA claims. F. Certification. Denied as moot. SO ORDERED. (KB) (Entered: 06/12/2025)	
112	06/12/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Final Pretrial Conference held on 6/12/2025. Court and the parties discuss the record in the case. Court has administrative record as it has been provided. Plaintiffs have also filed records. Court hears parties on the matter. Court will review defendants' opposition to the motions to Complete Record. Court will hear oral argument on phase 1 of the case on Monday, June 16th at 10am. Each side will have one hour for argument (plaintiffs in both cases will have one hour combined). Parties to discuss proposed phase 2 schedule on Monday. Court has off the record portion of hearing regarding possibility of settlement. If the case were to settle in part or in whole the parties shall inform the Clerk. (Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Matthew Brinckerhoff, Jessie Rossman, Lisa Mankofsky, Max Roller Selver, Olga Akselrod, Rachel Anne Meeropol, Sydney Kathryn Zazzaro, Gerard Cedrone, Christopher Pappavaselio, Phoebe Lockhart, Rachel Brown, Vanessa Azniv Arslanian, Nimrod Pitsker Elias, Astrid Carrete, Jordan Broadbent for plaintiffs and Anuj Khetarpal and Thomas Ports, Jr. for defendants) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/13/2025)	
111	06/13/2025	TRIAL BRIEF in Response to Plaintiffs' Opening Briefs by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services. (Khetarpal, Anuj) (Entered: 06/13/2025)	
113	06/13/2025	TRIAL BRIEF in Response to Defendants' Opening Brief on Phase 1 by All Plaintiffs. (Rossman, Jessie) (Entered: 06/13/2025)	
114	06/13/2025	Transcript of Final Pretrial held on June 12, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 7/7/2025. Redacted Transcript Deadline set for 7/14/2025. Release of Transcript Restriction set for 9/11/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 06/13/2025)	
115	06/13/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(DRK) (Entered: 06/13/2025)	
116	06/13/2025	NOTICE of Appearance by Ilann Margalit Maazel on behalf of Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers (Maazel, Ilann) (Entered: 06/13/2025)	
117	06/13/2025	NOTICE by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and	

#	Date	Proceeding Text	Source
		Human Services of Production of Administrative Record (Attachments: # 1 Designation and Certification of Administrative Record)(Khetarpal, Anuj) (Entered: 06/13/2025)	
118	06/13/2025	NOTICE by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers of Service (Agarwal, Shalini) (Entered: 06/13/2025)	
119	06/16/2025	ELECTRONIC NOTICE of Hearing. Hearing set for 6/16/2025 at 2:00pm. (In person with remote access provided) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/16/2025)	
120	06/16/2025	Judge William G. Young: STIPULATED PROTECTIVE ORDER entered. Granting (140) Joint Motion for Protective Order in case 1:25-cv-10814-WGY Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(KB) (Entered: 06/16/2025)	
121	06/16/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Bench Trial as to Phase 1 held on 6/16/2025.Court hears argument on Phase 1 of the case. Defendants ask Court to take Judicial Notice of the Federal Register Notices. Court takes Judicial Notice. Defendants move to admit into evidence 13 Certified records. No objection. Admitted as exhibit 1. Court takes the matter under advisement. Parties will inform the Court if they wish for the Court to reconvene in the afternoon or if they wish for the Court to hold off issuing a ruling as to Phase 1. The Court reconvenes in the afternoon. The Court announces the findings and rulings that it is able to make today. The challenged directives are vacated. A written order will issue. Defendants shall promptly comply with the order of the Court. Plaintiffs to submit a proposed partial but final judgment as to Phase 1 by June 17, 2025. The Court discusses evidence as to harm. The parties will meet and inform the Court if an evidentiary hearing regarding harm is necessary. (Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Kenneth Parreno, Jessie Rossman, Olga Akselrod, Rachel Anne Meeropol, Gerard Cedrone, Rachel Brown, Nimrod Pitsker Elias for plaintiffs and Anuj Khetarpal and Thomas Ports, Jr. for defendants) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/17/2025)	
122	06/17/2025	Proposed Document(s) submitted by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. Document received: Rule 54(b) Partial Final Judgment. (Brinckerhoff, Matthew) (Entered: 06/17/2025)	
123	06/18/2025	ELECTRONIC NOTICE of Hearing. Status Conference set for 6/18/2025 02:00 PM in Courtroom 18 (Remote only) before Judge William G. Young. This hearing will be conducted by video conference. Counsel of record will receive a video conference invite at the email registered in CM/ECF. If you have technical or compatibility issues with the technology, please notify the courtroom deputy of the session as soon as possible.Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here.Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/18/2025)	

#	Date	Proceeding Text	Source
124	06/18/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Status Conference re proposed judgments held on 6/18/2025. The Court hears from parties regarding proposed judgments and modifies judgments as stated. Plaintiffs' counsel shall re-submit the proposed judgments as modified by the Court. (Attorneys present: Olga Akselrod, Lisa Mankofsky, Suzanne Schlossberg, Jessie J. Rossman, Gerard Cedrone, Chris Pappavaselio, Phoebe Lockhart, Rachel M. Brown for plaintiffs and Anuj Khetarpal and Thomas Ports, Jr. for defendants)(Court Reporter: Richard Romanow at rhr3tubas@aol.com.) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/18/2025)	
125	06/18/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Leah Watson Filing fee: $ 125, receipt number AMADC-11076182 by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Exhibit A - Certificate)(Schlossberg, Suzanne) (Entered: 06/18/2025)	
126	06/18/2025	MOTION to Seal Lists of Grant Terminations by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers.(Brinckerhoff, Matthew) (Entered: 06/18/2025)	
127	06/18/2025	MEMORANDUM in Support re 126 MOTION to Seal Lists of Grant Terminations filed by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Brinckerhoff, Matthew) (Entered: 06/18/2025)	
128	06/18/2025	Proposed Document(s) submitted by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. Document received: Rule 54(b) Partial Final Judgment. (Attachments: # 1 Exhibit A, # 2 Exhibit B)(Brinckerhoff, Matthew) (Entered: 06/18/2025)	
129	06/19/2025	BRIEF by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers . (Meeropol, Rachel) (Entered: 06/19/2025)	
130	06/20/2025	MOTION to Dismiss for lack of jurisdiction and failure to state a claim by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services.(Khetarpal, Anuj) (Entered: 06/20/2025)	
131	06/20/2025	MEMORANDUM in Support re 130 MOTION to Dismiss for lack of jurisdiction and failure to state a claim filed by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services. (Khetarpal, Anuj) (Entered: 06/20/2025)	
132	06/20/2025	Opposition re 130 MOTION to Dismiss for lack of jurisdiction and failure to state a claim (Opposition as to Motion to Expedite) filed by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Parreno, Kenneth) (Entered: 06/20/2025)	
133	06/22/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 125 Motion for Leave to Appear Pro Hac Vice Added Leah Watson. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be	

#	Date	Proceeding Text	Source
		rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 06/22/2025)	
134	06/23/2025	Judge William G. Young: ORDER entered. re 126 MOTION to Seal Lists of Grant Terminations filed by American Public Health Association, Nicole Maphis, United Auto Workers, Peter Lurie, Brittany Charlton, Ibis Reproductive Health, Katie Edwards Motion to file under seal denied. Plaintiffs alternative proposal approved. (Sonnenberg, Elizabeth) (Entered: 06/23/2025)	
135	06/23/2025	Judge William G. Young: ELECTRONIC ORDER entered denying 126 Motion to Seal. See order 134 (Sonnenberg, Elizabeth) (Entered: 06/23/2025)	
136	06/23/2025	Judge William G. Young: ORDER entered. re 132 Opposition to Motion, filed by American Public Health Association, Nicole Maphis, United Auto Workers, Peter Lurie, Brittany Charlton, Ibis Reproductive Health, Katie Edwards The presently agreed deadlines are satisfactory. Request denied. (Sonnenberg, Elizabeth) (Entered: 06/23/2025)	
137	06/23/2025	Proposed Document(s) submitted by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. Document received: Revised Proposed Partial Final Judgment. (Attachments: # 1 Exhibit Exhibit A - May 27 Spreadsheet, # 2 Exhibit Exhibit B - June 13 Spreadsheet)(Schlossberg, Suzanne) (Entered: 06/23/2025)	
138	06/23/2025	Judge William G. Young: ORDER entered. RULE 54(b) PARTIAL FINAL JUDGMENT (Sonnenberg, Elizabeth) (Additional attachment(s) added on 6/23/2025: # 1 Exhibit A, # 2 Exhibit B) (MAP). (Main Document 138 replaced on 6/23/2025) (MAP). (Entered: 06/23/2025)	
139	06/23/2025	NOTICE OF APPEAL as to 138 Order, 84 Memorandum & ORDER, by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services. Fee Status: US Government. NOTICE TO COUNSEL: A Transcript Report/Order Form, which can be downloaded from the First Circuit Court of Appeals web site at http://www.ca1.uscourts.gov MUST be completed and submitted to the Court of Appeals. Counsel shall register for a First Circuit CM/ECF Appellate Filer Account at http://pacer.psc.uscourts.gov/cmecf. Counsel shall also review the First Circuit requirements for electronic filing by visiting the CM/ECF Information section at http://www.ca1.uscourts.gov/cmecf. US District Court Clerk to deliver official record to Court of Appeals by 7/14/2025. (Khetarpal, Anuj) (Entered: 06/23/2025)	
140	06/23/2025	MOTION to Stay re 138 Order by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services.(Khetarpal, Anuj) (Entered: 06/23/2025)	
141	06/23/2025	MEMORANDUM in Support re 140 MOTION to Stay re 138 Order filed by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services. (Khetarpal, Anuj) (Entered: 06/23/2025)	
142	06/23/2025	Certified and Transmitted Abbreviated Electronic Record on Appeal to US Court of Appeals re 139 Notice of Appeal. (MAP) (Entered: 06/23/2025)	
143	06/23/2025	Transcript of Bench Trial, Phase 1 (Closings) held on June 16, 2025, before Judge William G. Young. The Transcript may be	

#	Date	Proceeding Text	Source
		purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 7/14/2025. Redacted Transcript Deadline set for 7/24/2025. Release of Transcript Restriction set for 9/22/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 06/24/2025)	
144	06/23/2025	Transcript of Status Conference held on June 18, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 7/14/2025. Redacted Transcript Deadline set for 7/24/2025. Release of Transcript Restriction set for 9/22/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 06/24/2025)	
145	06/23/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 06/24/2025)	
146	06/24/2025	USCA Case Number 25-1611 for 139 Notice of Appeal,,, filed by Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services, Jay Bhattacharya. (MAP) (Entered: 06/24/2025)	
147	06/24/2025	Judge William G. Young: ORDER entered. (Sonnenberg, Elizabeth) (Entered: 06/24/2025)	
148	06/24/2025	Supplemental Record on Appeal transmitted to US Court of Appeals re 139 Notice of Appeal Documents included: ECF No. 147 (MAP) (Entered: 06/24/2025)	
149	06/30/2025	Opposition re 130 MOTION to Dismiss for lack of jurisdiction and failure to state a claim (Opposition as to Motion to Dismiss Phase 2 Claims) filed by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Parreno, Kenneth) (Entered: 06/30/2025)	
150	07/01/2025	NOTICE of Appearance by Leah Watson on behalf of Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers (Watson, Leah) (Entered: 07/01/2025)	
151	07/02/2025	Judge William G. Young: ORDER entered. FINDINGS OF FACT, RULINGS OF LAW, AND ORDER FOR PARTIAL SEPARATE AND FINAL JUDGMENTAssociated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(Sonnenberg, Elizabeth) (Entered: 07/02/2025)	
152	07/07/2025	Supplemental Record on Appeal transmitted to US Court of Appeals re 139 Notice of Appeal. (MAP) (Entered: 07/07/2025)	
153	07/09/2025	NOTICE by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services (Attachments: # 1 Certification of the Administrative Record)(Khetarpal, Anuj) (Entered: 07/09/2025)	
154	07/17/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Emily Gilman Filing fee: $ 125, receipt number AMADC-11127347 by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers. (Attachments: # 1 Exhibit A-Certificate)(Schlossberg, Suzanne) (Entered: 07/17/2025)	

#	Date	Proceeding Text	Source
155	07/17/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 154 Motion for Leave to Appear Pro Hac Vice Added Emily Gilman. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 07/17/2025)	
156	07/17/2025	NOTICE of Appearance by Samuel Hobbs on behalf of Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services (Hobbs, Samuel) (Entered: 07/17/2025)	
157	07/18/2025	OPINION of USCA as to 139 Notice of Appeal, filed by Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services, Jay Bhattacharya. The Department's Motion for a Stay is DENIED. (MAP) (Entered: 07/20/2025)	
158	07/18/2025	ORDER of USCA as to 139 Notice of Appeal, filed by Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services, Jay Bhattacharya (MAP) (Entered: 07/20/2025)	
159	07/21/2025	NOTICE of Appearance by Emily Danya Gilman on behalf of Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers (Gilman, Emily) (Entered: 07/21/2025)	
160	07/22/2025	ELECTRONIC NOTICE of Hearing. Status Conference set for 7/28/2025 11:00 AM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 07/22/2025)	
161	07/22/2025	Assented to MOTION for Extension of Time to 7/25/2025 to Plaintiffs Submission of Motion to Complete Phase 2 Administrative Record by Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers.(Brinckerhoff, Matthew) (Entered: 07/22/2025)	
162	07/23/2025	Judge William G. Young: ELECTRONIC ORDER entered allowed 161 Assented to MOTION for Extension of Time to 7/25/2025 to Plaintiffs Submission of Motion to Complete Phase 2 Administrative Record/ (MAP) (Entered: 07/23/2025)	
163	07/25/2025	JOINT STATEMENT of counsel regarding schedule for further proceedings. (Brinckerhoff, Matthew) (Entered: 07/25/2025)	
164	07/28/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Status Conference held on 7/28/2025. Parties discuss status of case and phase II. Court adopts schedule but modifies pretrial and bench trial date. Final Pretrial Conference set for September 2, 2025 at 10:00 AM. The Court will hear argument on motion to dismiss at the final pretrial conference. The Bench trial will occur no later than September 15, 2025. Court hears the parties on discovery. Court takes the legal arguments as to discovery under advisement. Court will issue an order on or after August 15th. Court hears parties on defendants' stipulation as to supplemental claims. If Court requires more data the Court will order it at that time, the stipulation may be sufficient. Court discusses application for stay in the Supreme Court and possible	

#	Date	Proceeding Text	Source
		outcomes. Final Pretrial Conference set for 9/2/2025 10:00 AM in Courtroom 18 (In person only with Remote Access Provided) before Judge William G. Young. Bench Trial set for 9/15/2025 09:00 AM in Courtroom 18 (In person only with Remote Access Provided) before Judge William G. Young.(Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Max Roller Selver, Suzanne Schlossberg, Katherine B. Dirks, Phoebe Lockhart, Anuj K. Khetarpal and Samuel Hobbs) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 07/29/2025)	
165	07/30/2025	Transcript of Status Conference held on July 28, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 8/20/2025. Redacted Transcript Deadline set for 9/2/2025. Release of Transcript Restriction set for 10/28/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 07/30/2025)	
166	07/30/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(DRK) (Entered: 07/30/2025)	
167	08/01/2025	JOINT STATEMENT of counsel and Stipulation Concerning Phase 2 Schedule. (Schlossberg, Suzanne) (Entered: 08/01/2025)	
168	08/14/2025	Judge William G. Young: ELECTRONIC ORDER entered approving re 167 JOINT STATEMENT of counsel and Stipulation Concerning Phase 2 Schedule. (KB) (Entered: 08/14/2025)	
169	08/15/2025	MEMORANDUM OF LAW by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services. (Khetarpal, Anuj) (Entered: 08/15/2025)	
170	08/19/2025	NOTICE by Jay Bhattacharya, Robert F. Kennedy, Jr., National Institutes of Health, United States Department of Health and Human Services of Production of Phase 2 AR Certifications (Khetarpal, Anuj) (Entered: 08/19/2025)	
171	08/26/2025	NOTICE of Appearance by Jennifer Herrmann on behalf of Brittany Charlton, Katie Edwards, American Public Health Association, Peter Lurie, Nicole Maphis, Ibis Reproductive Health, United Auto Workers (Herrmann, Jennifer) (Entered: 08/26/2025)	
172	08/29/2025	NOTICE OF COURTROOM CHANGE: The hearing on 9/2/2025 will occur in Courtroom 17. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 08/29/2025)	
173	09/02/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Final Pretrial Conference held on 9/2/2025. Court addresses Supreme Court order. Court takes recess for parties to confer. Court continues hearing until Thursday at 10:00AM. Pretrial deadlines are extended accordingly. Final Pretrial Conference set for 9/4/2025 10:00 AM in Courtroom 10 (In person with remote access provided) before Judge William G. Young. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on	

#	Date	Proceeding Text	Source
		www.mad.uscourts.gov or contact the session here. (Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Kenneth Parreno, Alejandro Ortiz, Jessie J. Rossman, Olga Akselrod, Gerard J. Cedrone, Phoebe Lockhart, Vanessa Azniv Arslanian for plaintiffs and Samuel Hobbs and Anuj Khetarpal for defendants) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/02/2025)	
174	09/03/2025	ELECTRONIC NOTICE OF RESCHEDULING: At request of the parties the Final Pretrial Conference is reset for 9/9/2025 03:30 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Bench trial is reset for 9/22/2025. Deadlines are extended accordingly. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here.Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/03/2025)	
175	09/04/2025	Transcript of Final Pretrial Conference held on September 2, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 9/25/2025. Redacted Transcript Deadline set for 10/6/2025. Release of Transcript Restriction set for 12/3/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(DRK) (Entered: 09/04/2025)	
176	09/04/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(DRK) (Entered: 09/04/2025)	
177	09/08/2025	ELECTRONIC NOTICE OF RESCHEDULING: At request of the parties, the Final Pretrial Conference is reset for 9/18/2025 02:00 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Bench Trial is reset for 10/6/2025 09:00 AM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/08/2025)	
178	09/17/2025	ELECTRONIC NOTICE Canceling Hearing. Due to a conflict in the Court's schedule the Final Pretrial Conference set for 9/18/2025 is cancelled and will be rescheduled. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/17/2025)	
179	09/18/2025	ELECTRONIC NOTICE OF RESCHEDULING: At request of the parties, the Final Pretrial Conference is reset for 9/30/2025 02:00 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Bench Trial tentatively reset for 10/14/2025 09:00 AM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Final Pretrial Conference set for 9/30/2025 02:00 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/18/2025)	

#	Date	Proceeding Text	Source
180	09/25/2025	ELECTRONIC NOTICE Cancelling Hearings. The Final Pretrial Conference set for 9/30/2025 and the Bench Trial set for 10/14/2025 are cancelled and will be rescheduled for dates to be determined. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/25/2025)	Events since last full update

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End of Document

1:25cv10814, Commonwealth Of Massachusetts Et Al V. Kennedy, Jr. Et Al

US District Court Docket

United States District Court, Massachusetts

(Boston)

This case was retrieved on 09/25/2025

Header

Case Number: 1:25cv10814
Date Filed: 04/04/2025
Assigned To: Judge William G. Young
Nature of Suit: Other Statutes - Administrative Procedure Act/Review or Appeal of Agency Decision (899)
Cause: Administrative Procedure Act
Lead Docket: None
Other Docket: 1:25cv10787, USCA - First Circuit, 25-01612
Jurisdiction: Federal Question

Class Code: Open
Statute: 05:702
Jury Demand: None
Demand Amount: $0
NOS Description: Other Statutes - Administrative Procedure Act/Review or Appeal of Agency Decision

Participants

Litigants

Commonwealth of Massachusetts
Plaintiff

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National Center for Advancing Translational Sciences **Defendant**	Thomas Ports , Jr LEAD ATTORNEY;ATTORNEY TO BE NOTICED DOJ-Enrd P.O. Box 875 Ben Franklin Station Washington, DC 20044 USA 202-307-1105 Email:Thomas.Ports@usdoj.Gov Anuj K. Khetarpal ATTORNEY TO BE NOTICED United States Attorney's Office 1 Courthouse Way Suite 9200 Boston, MA 02210 USA 617-823-6325 Email:Anuj.Khetarpal@usdoj.Gov Samuel Hobbs ATTORNEY TO BE NOTICED DOJ-Civ Corporate Financial Litigation 1100 L St Nw Room 7210 Washington, DC 20005 USA 202-616-8077 Email:Samuel.Hobbs@usdoj.Gov
John E. Fogarty International Center for Advanced Study in the Health Sciences **Defendant**	Thomas Ports , Jr LEAD ATTORNEY;ATTORNEY TO BE NOTICED DOJ-Enrd P.O. Box 875 Ben Franklin Station Washington, DC 20044 USA 202-307-1105 Email:Thomas.Ports@usdoj.Gov

Litigants	Attorneys
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National Center for Complementary and Integrative Health **Defendant**	Thomas Ports , Jr LEAD ATTORNEY;ATTORNEY TO BE NOTICED DOJ-Enrd P.O. Box 875 Ben Franklin Station Washington, DC 20044 USA 202-307-1105 Email:Thomas.Ports@usdoj.Gov Anuj K. Khetarpal ATTORNEY TO BE NOTICED United States Attorney's Office 1 Courthouse Way Suite 9200 Boston, MA 02210 USA 617-823-6325 Email:Anuj.Khetarpal@usdoj.Gov Samuel Hobbs ATTORNEY TO BE NOTICED DOJ-Civ Corporate Financial Litigation 1100 L St Nw Room 7210 Washington, DC 20005 USA 202-616-8077 Email:Samuel.Hobbs@usdoj.Gov
NIH Center for Scientific Review **Defendant**	Thomas Ports , Jr LEAD ATTORNEY;ATTORNEY TO BE NOTICED DOJ-Enrd P.O. Box 875 Ben Franklin Station Washington, DC 20044 USA 202-307-1105 Email:Thomas.Ports@usdoj.Gov Anuj K. Khetarpal ATTORNEY TO BE NOTICED United States Attorney's Office 1 Courthouse Way Suite 9200 Boston, MA 02210 USA 617-823-6325 Email:Anuj.Khetarpal@usdoj.Gov Samuel Hobbs ATTORNEY TO BE NOTICED DOJ-Civ

Litigants	Attorneys
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The American Association of State Colleges and Universities (AASCU) **Amicus**	Amish Aajay Shah ATTORNEY TO BE NOTICED Ropes & Gray LLP 2099 Pennsylvania Avenue, N.W. Washington, DC 20006 USA 202-508-4791 Email:Amish.Shah@ropesgray.Com Stephanie A. Webster ATTORNEY TO BE NOTICED Ropes & Gray LLP 2099 Pennsylvania Avenue, N.W. Suite 1200 Washington, DC 20006-6807 USA 202-508-4859 Fax: 202-383-9334 Email:Stephanie.Webster@ropesgray.Com
The American Council on Education (ACE) **Amicus**	Amish Aajay Shah ATTORNEY TO BE NOTICED Ropes & Gray LLP 2099 Pennsylvania Avenue, N.W. Washington, DC 20006 USA 202-508-4791 Email:Amish.Shah@ropesgray.Com Stephanie A. Webster ATTORNEY TO BE NOTICED Ropes & Gray LLP 2099 Pennsylvania Avenue, N.W. Suite 1200 Washington, DC 20006-6807 USA 202-508-4859 Fax: 202-383-9334 Email:Stephanie.Webster@ropesgray.Com
The Association of American Universities (AAU) **Amicus**	Amish Aajay Shah ATTORNEY TO BE NOTICED Ropes & Gray LLP 2099 Pennsylvania Avenue, N.W. Washington, DC 20006 USA 202-508-4791 Email:Amish.Shah@ropesgray.Com

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The Association of Governing Boards of Universities and Colleges (AGB) **Amicus**	Amish Aajay Shah ATTORNEY TO BE NOTICED Ropes & Gray LLP 2099 Pennsylvania Avenue, N.W. Washington, DC 20006 USA 202-508-4791 Email:Amish.Shah@ropesgray.Com
	Stephanie A. Webster ATTORNEY TO BE NOTICED Ropes & Gray LLP 2099 Pennsylvania Avenue, N.W. Suite 1200 Washington, DC 20006-6807 USA 202-508-4859 Fax: 202-383-9334 Email:Stephanie.Webster@ropesgray.Com
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COGR **Amicus**	Amish Aajay Shah ATTORNEY TO BE NOTICED Ropes & Gray LLP 2099 Pennsylvania Avenue, N.W. Washington, DC 20006 USA 202-508-4791 Email:Amish.Shah@ropesgray.Com
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The National Association of Independent Colleges and Universities (NAICU)	Amish Aajay Shah ATTORNEY TO BE NOTICED

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Proceedings

#	Date	Proceeding Text	Source
1	04/04/2025	COMPLAINT For Declaratory and Injunctive Relief against All Defendants Filing fee: $ 405, receipt number AMADC-10933014 (Fee Status: Filing Fee paid), filed by State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Wisconsin, Commonwealth of Massachusetts, State of California, State of Maryland, State of Washington, State of Arizona, State of Colorado, State of Delaware, State of Hawaii, State of Minnesota. (Attachments: # 1 Civil Cover Sheet, # 2 Category Form)(Cedrone, Gerard) Modified on 4/4/2025 to correct docket text (SP). (Entered: 04/04/2025)	
2	04/04/2025	ELECTRONIC NOTICE of Case Assignment. Judge Brian E. Murphy assigned to case. If the trial Judge issues an Order of Reference of any matter in this case to a Magistrate Judge, the matter will be transmitted to Magistrate Judge M. Page Kelley. (NMC) (Entered: 04/04/2025)	
3	04/04/2025	Summons Issued as to All Defendants. Counsel receiving this notice electronically should download this summons, complete one for each defendant and serve it in accordance with Fed.R.Civ.P. 4 and LR 4.1. Summons will be mailed to plaintiff(s) not receiving notice electronically for completion of service. (SP) (Entered: 04/04/2025)	
4	04/04/2025	NOTICE of Appearance by Rachel M. Brown on behalf of Commonwealth of Massachusetts (Brown, Rachel) (Entered: 04/04/2025)	
5	04/04/2025	NOTICE of Appearance by Chris Pappavaselio on behalf of Commonwealth of Massachusetts (Pappavaselio, Chris) (Entered: 04/04/2025)	
6	04/04/2025	NOTICE of Appearance by Vanessa Azniv Arslanian on behalf of Commonwealth of Massachusetts (Arslanian, Vanessa) (Entered: 04/04/2025)	
7	04/04/2025	NOTICE of Appearance by Allyson T Slater on behalf of Commonwealth of Massachusetts (Slater, Allyson) (Entered: 04/04/2025)	
8	04/04/2025	Emergency MOTION for Temporary Restraining Order by State of Nevada, State of New Jersey, State of New York, State of Oregon, State of Rhode Island, State of Wisconsin, Commonwealth of Massachusetts, State of California, State of Maryland, State of Washington, State of Arizona, State of	

#	Date	Proceeding Text	Source
		Delaware, State of Hawaii. (Attachments: # 1 Text of Proposed Order)(Cedrone, Gerard) (Entered: 04/04/2025)	
9	04/04/2025	MEMORANDUM in Support re 8 Emergency MOTION for Temporary Restraining Order filed by State of Nevada, State of New Jersey, State of New York, State of Oregon, State of Rhode Island, State of Wisconsin, Commonwealth of Massachusetts, State of California, State of Maryland, State of Washington, State of Arizona, State of Delaware, State of Hawaii. (Cedrone, Gerard) (Entered: 04/04/2025)	
10	04/04/2025	MOTION for Leave to File Excess Pages (re ECF No. 9, Memorandum in Support of Motion for Temproary Restraining Order) by State of Nevada, State of New Jersey, State of New York, State of Oregon, State of Rhode Island, State of Wisconsin, Commonwealth of Massachusetts, State of California, State of Maryland, State of Washington, State of Arizona, State of Delaware, State of Hawaii.(Cedrone, Gerard) (Entered: 04/04/2025)	
11	04/04/2025	NOTICE of Appearance by Katherine B. Dirks on behalf of Commonwealth of Massachusetts (Dirks, Katherine) (Entered: 04/04/2025)	
12	04/04/2025	DECLARATION re 8 Emergency MOTION for Temporary Restraining Order by State of Nevada, State of New Jersey, State of New York, State of Oregon, State of Rhode Island, State of Wisconsin, Commonwealth of Massachusetts, State of California, State of Maryland, State of Washington, State of Arizona, State of Delaware, State of Hawaii. (Attachments: # 1 Exhibit 1, EO 14151, # 2 Exhibit 2, EO 14168, # 3 Exhibit 3, EO 14173, # 4 Exhibit 4, HHS Directive 2.10.25, # 5 Exhibit 5, Lauer Memo 2.12.25, # 6 Exhibit 6, NIH Guidance 2.13.25, # 7 Exhibit 7, DOGE Tweet 2.28.25, # 8 Exhibit 8, DEI Staff Guidance 3.4.25, # 9 Exhibit 9, Bulls Email 3.13.25, # 10 Exhibit 10, Staff Guidance and Appendices 3.25.25, # 11 Exhibit 11, NIHGPS Excerpts, # 12 Exhibit 12, MA Barton Dec., # 13 Exhibit 13, AZ Wilder Dec., # 14 Exhibit 14, CA Madanat Dec., # 15 Exhibit 15, CA Raman Dec., # 16 Exhibit 16, DE Garcia-Diaz Dec., # 17 Exhibit 17, HI Syrmos Dec., # 18 Exhibit 18, MD Pines Dec., # 19 Exhibit 19, MD Jarrell Dec., # 20 Exhibit 20, NJ Farmer Dec., # 21 Exhibit 21, NV Tracy Dec., # 22 Exhibit 22, NV Hatchett Dec., # 23 Exhibit 23, NY Murphy Dec., # 24 Exhibit 24, NY Shurtleff Dec., # 25 Exhibit 25, NY Hequembourg Dec., # 26 Exhibit 26, RI Jenkins Dec., # 27 Exhibit 27, WA Ostendorf Dec., # 28 Exhibit 28, WA Supp. Ostendorf Dec., # 29 Exhibit 29, WI Grejner-Brzezinska Dec., # 30 Exhibit 30, WI Moreno Dec., # 31 Exhibit 31, WI Nambisan Dec., # 32 Exhibit 32, WI OConnor Dec., # 33 Exhibit 33, WI Shorey Dec., # 34 Exhibit 34, OR Barr-Gillespie Dec., # 35 Exhibit 35, SF Philip Dec., # 36 Exhibit 36, CA Maldonado Dec., # 37 Exhibit 37, Berg Dec., # 38 Exhibit 38, Jaime Dec.)(Pappavaselio, Chris) (Entered: 04/04/2025)	
13	04/04/2025	NOTICE of Appearance by Gerard J. Cedrone on behalf of Commonwealth of Massachusetts (Cedrone, Gerard) (Entered: 04/04/2025)	
14	04/04/2025	Judge Brian E. Murphy: ELECTRONIC ORDER granting 10 Motion for Leave to File Excess Pages. (BIB) (Entered: 04/04/2025)	
15	04/04/2025	Judge Brian E. Murphy: SHORT ORDER OF NOTICE...Plaintiffs' Complaint, Motion for Temporary Restraining Order and all supporting documents filed in this case shall be served on the Defendants, with a copy of this Order no later than Monday, April 7, 2025. Defendants shall file a response to the 8 Motion for Temporary Restraining Order no later than Wednesday, April 9,	

#	Date	Proceeding Text	Source
		2025.A hearing is SCHEDULED for Tuesday, April 15, 2025 at 2:00 p.m. in Courtroom #12 before Judge Brian E. Murphy. (BIB) (Entered: 04/04/2025)	
16	04/04/2025	MOTION for Leave to Appear Pro Hac Vice for admission of James C. Luh and Michael Drezner Filing fee: $ 250, receipt number AMADC-10934368 by State of Maryland.(Brown, Rachel) (Additional attachment(s) added on 4/4/2025: # 1 Certificate of James C. Luh, # 2 Certificate of Michael Drezner) (MBM). (Entered: 04/04/2025)	
17	04/04/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Emilio Varanini, Sophia T. Tonnu, Daniel D. Ambar, Nimrod Pitsker Elias, and Ketakee R. Kane Filing fee: $ 625, receipt number AMADC-10934443 by State of California. (Attachments: # 1 Certificate of Daniel Ambar, # 2 Certificate of Emilio Varanini, # 3 Certificate of Ketakee R. Kane, # 4 Certificate of Nimrod Pitsker Elias, # 5 Certificate of Sophia T. Tonnu)(Brown, Rachel) (Entered: 04/04/2025)	
18	04/04/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Peter J. Farrell Filing fee: $ 125, receipt number AMADC-10934469 by State of Minnesota. (Attachments: # 1 Certificate of Peter J. Farrell)(Brown, Rachel) (Entered: 04/04/2025)	
19	04/04/2025	Judge Brian E. Murphy: AMENDED SHORT ORDER OF NOTICE...Plaintiffs shall file a reply brief no later than 3:00 p.m. on Friday, April 11, 2025. (BIB) (Entered: 04/04/2025)	
20	04/04/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Shannon Stevenson and Lauren Peach Filing fee: $ 250, receipt number AMADC-10934509 by State of Colorado. (Attachments: # 1 Certificate of Shannon Stevenson, # 2 Certificate of Lauren Peach)(Brown, Rachel) (Entered: 04/04/2025)	
21	04/04/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Molly Thomas-Jensen and Rabia Muqaddam Filing fee: $ 250, receipt number AMADC-10934710 by State of New York. (Attachments: # 1 Certificate of Molly Thomas-Jensen, # 2 Certificate of Rabia Muqaddam)(Brown, Rachel) (Entered: 04/04/2025)	
22	04/04/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Christina L. Beatty-Walters Filing fee: $ 125, receipt number AMADC-10934742 by State of Oregon. (Attachments: # 1 Certificate of Christina L. Beatty-Walters)(Brown, Rachel) (Entered: 04/04/2025)	
23	04/04/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Andrew R.W. Hughes and Tyler S. Roberts Filing fee: $ 250, receipt number AMADC-10934780 by State of Washington. (Attachments: # 1 Certificate of Andrew R. W. Hughes, # 2 Certificate of Tyler S. Roberts)(Brown, Rachel) (Entered: 04/04/2025)	
24	04/04/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Hilary Chan Filing fee: $ 125, receipt number AMADC-10934896 by State of California. (Attachments: # 1 Certificate of Hilary Chan)(Brown, Rachel) (Entered: 04/04/2025)	
25	04/04/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 16 Motion for Leave to Appear Pro Hac Vice Added James C. Luh and Michael Drezner. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions	

#	Date	Proceeding Text	Source
		https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/04/2025)	
26	04/07/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 18 Motion for Leave to Appear Pro Hac Vice Added Peter J. Farrell. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/07/2025)	
27	04/07/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 22 Motion for Leave to Appear Pro Hac Vice Added Christina L. Beatty-Walters. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MBM) (Entered: 04/07/2025)	
28	04/07/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 23 Motion for Leave to Appear Pro Hac Vice Added Andrew R.W. Hughes and Tyler S. Roberts. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/07/2025)	
29	04/07/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 24 Motion for Leave to Appear Pro Hac Vice Added Hilary Chan. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/07/2025)	
30	04/07/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 20 Motion for Leave to Appear Pro Hac Vice Added Shannon Stevenson and Lauren Peach. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions	

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		https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/07/2025)	
31	04/07/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 21 Motion for Leave to Appear Pro Hac Vice Added Molly Thomas-Jensen and Rabia Muqaddam. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/07/2025)	
32	04/07/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 17 Motion for Leave to Appear Pro Hac Vice Added Emilio Varanini, Sophia T. Tonnu, Daniel D. Ambar, Nimrod Pitsker Elias, and Ketakee R. Kane. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/07/2025)	
33	04/07/2025	NOTICE of Appearance by James C. Luh on behalf of State of Maryland (Luh, James) (Entered: 04/07/2025)	
34	04/07/2025	NOTICE of Appearance by Anuj K. Khetarpal on behalf of Robert F. Kennedy, Jr., United States Department of Health and Human Services, Jayanta Bhattacharya, National Institutes of Health, National Cancer Institute, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute on Deafness and Other Communication Disorders, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute on Drug Abuse, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute on Minority Health and Health Disparities, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Library of Medicine, National Center for Advancing Translational Sciences, John E. Fogarty International Center for Advanced Study in the Health Sciences, National Center for Complementary and Integrative Health, NIH Center for Scientific Review (Khetarpal, Anuj) (Entered: 04/07/2025)	
35	04/07/2025	NOTICE of Appearance by Molly Thomas-Jensen on behalf of State of New York (Thomas-Jensen, Molly) (Entered: 04/07/2025)	
36	04/07/2025	NOTICE of Appearance by Peter Farrell on behalf of State of Minnesota (Farrell, Peter) (Entered: 04/07/2025)	

#	Date	Proceeding Text	Source
37	04/07/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Joshua G. Nomkin Filing fee: $ 125, receipt number AMADC-10937197 by State of Arizona. (Attachments: # 1 Certificate of Joshua G. Nomkin)(Brown, Rachel) (Entered: 04/07/2025)	
38	04/07/2025	NOTICE of Appearance by Daniel Ambar on behalf of State of California (Ambar, Daniel) (Entered: 04/07/2025)	
39	04/07/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 37 Motion for Leave to Appear Pro Hac Vice Added Joshua G. Nomkin. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/07/2025)	
40	04/07/2025	NOTICE of Appearance by Rabia Muqaddam on behalf of State of New York (Muqaddam, Rabia) (Entered: 04/07/2025)	
41	04/07/2025	NOTICE of Appearance by Sophia TonNu on behalf of State of California (TonNu, Sophia) (Entered: 04/07/2025)	
42	04/07/2025	NOTICE of Appearance by Emilio Eugene Varanini, IV on behalf of State of California (Varanini, Emilio) (Entered: 04/07/2025)	
43	04/07/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Kathleen Boergers Filing fee: $ 125, receipt number AMADC-10938287 by State of California. (Attachments: # 1 Certificate of Kathleen Boergers)(Brown, Rachel) (Entered: 04/07/2025)	
44	04/08/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 43 Motion for Leave to Appear Pro Hac Vice Added Kathleen Boergers. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/08/2025)	
45	04/08/2025	NOTICE of Appearance by Lauren Kelsey Peach on behalf of State of Colorado (Peach, Lauren) (Entered: 04/08/2025)	
46	04/08/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Lynn K. Lodahl Filing fee: $ 125, receipt number AMADC-10939698 by State of Wisconsin. (Attachments: # 1 Certificate of Lynn K. Lodahl)(Brown, Rachel) (Entered: 04/08/2025)	
47	04/08/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Jordan Broadbent Filing fee: $ 125, receipt number AMADC-10939713 by State of Rhode Island. (Attachments: # 1 Certificate of Jordan Broadbent)(Brown, Rachel) (Entered: 04/08/2025)	
48	04/08/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Kalikoonlani D. Fernandes and David D. Day Filing fee: $ 250, receipt number AMADC-10940489 by State of Hawaii. (Attachments: # 1 Certificate of Kalikoonlani D. Fernandes, # 2 Certificate of David D. Day)(Brown, Rachel) (Entered: 04/08/2025)	
49	04/08/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 46 Motion for Leave to Appear Pro Hac Vice Added Lynn K. Lodahl. Attorneys admitted Pro Hac Vice must have an individual	

#	Date	Proceeding Text	Source
		PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/08/2025)	
50	04/08/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 47 Motion for Leave to Appear Pro Hac Vice Added Jordan Broadbent. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MBM) (Entered: 04/08/2025)	
51	04/08/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 48 Motion for Leave to Appear Pro Hac Vice Added Kalikoonlani D. Fernandes and David D. Day. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MBM) (Entered: 04/08/2025)	
52	04/08/2025	NOTICE of Appearance by Jordan Broadbent on behalf of State of Rhode Island (Broadbent, Jordan) (Entered: 04/08/2025)	
53	04/08/2025	NOTICE of Appearance by Joshua Nomkin on behalf of State of Arizona (Nomkin, Joshua) (Entered: 04/08/2025)	
54	04/08/2025	SUMMONS Returned Executed by State of Delaware, State of California, Commonwealth of Massachusetts, State of Wisconsin, State of Oregon, State of Nevada, State of New Jersey, State of New York, State of Colorado, State of Maryland, State of Minnesota, State of New Mexico, State of Rhode Island, State of Hawaii, State of Washington, State of Arizona. (Attachments: # 1 Exhibit Declaration of Service)(Pappavaselio, Chris) (Entered: 04/08/2025)	
55	04/08/2025	NOTICE of Appearance by Kalikoonalani Diara Fernandes on behalf of State of Hawaii (Fernandes, Kalikoonalani) (Entered: 04/08/2025)	
56	04/08/2025	NOTICE of Appearance by David Dana Day on behalf of State of Hawaii (Day, David) (Entered: 04/08/2025)	
57	04/08/2025	NOTICE of Appearance by Thomas Ports, Jr on behalf of Robert F. Kennedy, Jr., United States Department of Health and Human Services, Jayanta Bhattacharya, National Institutes of Health, National Cancer Institute, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute on Deafness and Other Communication Disorders, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and	

#	Date	Proceeding Text	Source
		Digestive and Kidney Diseases, National Institute on Drug Abuse, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute on Minority Health and Health Disparities, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Library of Medicine, National Center for Advancing Translational Sciences, John E. Fogarty International Center for Advanced Study in the Health Sciences, National Center for Complementary and Integrative Health, NIH Center for Scientific Review (Ports, Thomas) (Entered: 04/08/2025)	
58	04/08/2025	Assented to MOTION to Set a Briefing Schedule on Plaintiffs' Motion for a Preliminary Injunction and NOTICE of Withdrawal of Plaintiffs' Motion for a Temporary Restraining Order re 8 Emergency MOTION for Temporary Restraining Order by State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Wisconsin, Commonwealth of Massachusetts, State of California, State of Maryland, State of Washington, State of Arizona, State of Colorado, State of Delaware, State of Hawaii, State of Minnesota.(Cedrone, Gerard) (Entered: 04/09/2025)	
59	04/09/2025	Judge Brian E. Murphy: ELECTRONIC ORDER GRANTING 58 Assented to MOTION to Set a Briefing Schedule on Plaintiffs' Motion for a Preliminary Injunction and NOTICE of Withdrawal of Plaintiffs' Motion for a Temporary Restraining Order. The 8 Emergency Motion for a Temporary Restraining Order is WITHDRAWN. Briefing schedule for the Motion for Preliminary Injunction is ADOPTED and hearing is set.BRIEFING SCHEDULE:Plaintiffs' Motion for Preliminary Injunction shall be filed 4/14/2025.Oppositions to Motion for Preliminary Injunction shall be filed by 4/30/2025.Replies shall be filed by 5/5/2025.NOTICE OF HEARING:Hearing on Motion for Preliminary Injunction is scheduled for 5/9/2025 at 1:30 p.m. in Courtroom 12 (In person only) before Judge Brian E. Murphy. (BIB) (Entered: 04/09/2025)	
60	04/09/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Vanessa L. Kassab Filing fee: $ 125, receipt number AMADC-10942197 by State of Delaware. (Attachments: # 1 Certificate of Vanessa Kassab)(Brown, Rachel) (Entered: 04/09/2025)	
61	04/09/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Astrid Carrete Filing fee: $ 125, receipt number AMADC-10942213 by State of New Mexico. (Attachments: # 1 Certificate of Astrid Carrete)(Brown, Rachel) (Entered: 04/09/2025)	
62	04/09/2025	NOTICE of Appearance by Nimrod Pitsker Elias on behalf of State of California (Elias, Nimrod) (Entered: 04/09/2025)	
63	04/09/2025	NOTICE of Appearance by Tyler S. Roberts on behalf of State of Washington (Roberts, Tyler) (Entered: 04/09/2025)	
64	04/09/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Heidi Parry Stern Filing fee: $ 125, receipt number AMADC-10942950 by State of Nevada. (Attachments: # 1 Certificate of Heidi Parry Stern)(Brown, Rachel) (Entered: 04/09/2025)	
65	04/09/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Nancy Trasande and Bryce K. Hurst Filing fee: $ 250, receipt number AMADC-10942961 by State of New Jersey. (Attachments: # 1 Certificate of Nancy Trasande, # 2 Certificate of Bryce K. Hurst)(Brown, Rachel) (Entered: 04/09/2025)	
66	04/09/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 60 Motion for Leave to Appear Pro Hac Vice Added Vanessa L. Kassab. Attorneys admitted Pro Hac Vice must have an individual	

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		upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MBM) (Entered: 04/09/2025)	
67	04/09/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 61 Motion for Leave to Appear Pro Hac Vice Added Astrid Carrete. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/09/2025)	
68	04/09/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 64 Motion for Leave to Appear Pro Hac Vice Added Heidi Parry Stern. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MBM) (Entered: 04/09/2025)	
69	04/09/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 65 Motion for Leave to Appear Pro Hac Vice Added Nancy Trasande and Bryce K. Hurst. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/09/2025)	
70	04/09/2025	NOTICE of Appearance by Hilary Ann Burke Chan on behalf of State of California (Burke Chan, Hilary) (Entered: 04/09/2025)	
71	04/10/2025	NOTICE of Appearance by Shannon Wells Stevenson on behalf of State of Colorado (Stevenson, Shannon) (Entered: 04/10/2025)	
72	04/10/2025	NOTICE of Appearance by Heidi Parry Stern on behalf of State of Nevada (Stern, Heidi) (Entered: 04/10/2025)	
73	04/14/2025	NOTICE of Appearance by Bryce Kelly Hurst on behalf of State of New Jersey (Hurst, Bryce) (Entered: 04/14/2025)	
74	04/14/2025	NOTICE of Appearance by Nancy Trasande on behalf of State of New Jersey (Trasande, Nancy) (Entered: 04/14/2025)	
75	04/14/2025	AMENDED COMPLAINT for Declaratory and Injunctive Relief against All Defendants, filed by State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Wisconsin, Commonwealth of Massachusetts, State of California, State of Maryland, State of Washington, State of Arizona, State of Colorado, State of Delaware, State of Hawaii, State of Minnesota. (Attachments: # 1	

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		Exhibit 1 (Notice Pause Directive), # 2 Exhibit 2 (Secretarial Directive), # 3 Exhibit 3 (Lauer Memorandum), # 4 Exhibit 4 (Supplemental Lauer Memorandum), # 5 Exhibit 5 (Priorities Directive), # 6 Exhibit 6 (Award Revision Guidance), # 7 Exhibit 7 (Revised Priorities Directive))(Cedrone, Gerard) (Entered: 04/14/2025)	
76	04/14/2025	MOTION for Preliminary Injunction by State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Wisconsin, Commonwealth of Massachusetts, State of California, State of Maryland, State of Washington, State of Arizona, State of Delaware, State of Hawaii, State of Minnesota. (Attachments: # 1 Text of Proposed Order)(Cedrone, Gerard) (Entered: 04/14/2025)	
77	04/14/2025	DECLARATION re 76 MOTION for Preliminary Injunction by State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Wisconsin, Commonwealth of Massachusetts, State of California, State of Maryland, State of Washington, State of Arizona, State of Delaware, State of Hawaii, State of Minnesota. (Attachments: # 1 Exhibit 1, EO 14151, # 2 Exhibit 2, EO 14168, # 3 Exhibit 3, EO 14173, # 4 Exhibit 4, HHS Directive 2.10.25, # 5 Exhibit 5, Lauer Memo 2.12.25, # 6 Exhibit 6, NIH Guidance 2.13.25, # 7 Exhibit 7, DOGE Tweet 2.28.25, # 8 Exhibit 8, DEI Staff Guidance 3.4.25, # 9 Exhibit 9, Bulls Email 3.13.25, # 10 Exhibit 10, Staff Guidance and Appendices 3.25.25 (Updated), # 11 Exhibit 11, NIHGPS Excerpts (Updated), # 12 Exhibit 12, MA Barton Dec., # 13 Exhibit 13, AZ Wilder Dec., # 14 Exhibit 14, CA Madanat Dec., # 15 Exhibit 15, CA Raman Dec., # 16 Exhibit 16, DE Garcia-Diaz Dec., # 17 Exhibit 17, HI Syrmos Dec. (Updated), # 18 Exhibit 18, MD Pines Dec., # 19 Exhibit 19, MD Jarrell Dec. (Updated), # 20 Exhibit 20, NJ Farmer Dec., # 21 Exhibit 21, NV Tracy Dec., # 22 Exhibit 22, NV Hatchett Dec., # 23 Exhibit 23, NY Murphy Dec., # 24 Exhibit 24, NY Shurtleff Dec., # 25 Exhibit 25, NY Hequembourg Dec., # 26 Exhibit 26, RI Jenkins Dec., # 27 Exhibit 27, WA Ostendorf Dec., # 28 Exhibit 28, WA Supp. Ostendorf Dec., # 29 Exhibit 29, WI Grejner-Brzezinska Dec., # 30 Exhibit 30, WI Moreno Dec., # 31 Exhibit 31, WI Nambisan Dec., # 32 Exhibit 32, WI OConnor Dec., # 33 Exhibit 33, WI Shorey Dec., # 34 Exhibit 34, OR Barr-Gillespie Dec., # 35 Exhibit 35, SF Philip Dec., # 36 Exhibit 36, CA Maldonado Dec., # 37 Exhibit 37, Berg Dec., # 38 Exhibit 38, Jaime Dec., # 39 Exhibit 39 Jan 21 Pause Guidance, # 40 Exhibit 40 Hutchings Dec, # 41 Exhibit 41 Bulls Deposition, # 42 Exhibit 42 Atlantic Article, # 43 Exhibit 43 Advisory Council Agendas, # 44 Exhibit 44 AACR Article, # 45 Exhibit 45 MA Barton Supp Dec, # 46 Exhibit 46 AZ Morton Dec, # 47 Exhibit 47 AZ Wilder Supp Dec, # 48 Exhibit 48 CA Crawford Dec, # 49 Exhibit 49 CA Kitchell Dec, # 50 Exhibit 50 WI Pool Dec, # 51 Exhibit 51 NJ Kean Dec, # 52 Exhibit 52 NJ Pelesko Dec, # 53 Exhibit 53 NJ Farmer Supp Dec, # 54 Exhibit 54 NM Reddi Dec, # 55 Exhibit 55 NM Lusetti Dec, # 56 Exhibit 56 NM Richards Dec, # 57 Exhibit 57 OR Forrest Dec, # 58 Exhibit 58 OR Tankersly Dec, # 59 Exhibit 59 OR Razdan Dec, # 60 Exhibit 60 RI Jenkins Supp Dec, # 61 Exhibit 61 Berg Supp Dec, # 62 Exhibit 62 CA Raman Supp Dec, # 63 Exhibit 63 CA Riggs Supp Dec, # 64 Exhibit 64 MN Shashank Dec, # 65 Exhibit 65 CA Collard Dec)(Pappavaselio, Chris) (Entered: 04/14/2025)	
78	04/14/2025	MEMORANDUM in Support re 76 MOTION for Preliminary Injunction filed by State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Wisconsin, Commonwealth of Massachusetts,	

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		State of California, State of Maryland, State of Washington, State of Arizona, State of Delaware, State of Hawaii, State of Minnesota. (Cedrone, Gerard) (Entered: 04/14/2025)	
79	04/17/2025	MOTION for Leave to File Amici Curiae Brief (unopposed) by The Association of American Medical Colleges, The American Association of State Colleges and Universities, The American Council on Education, The Association of American Universities, The Association of Governing Boards of Universities and Colleges, The Association of Public and Land-Grant Universities, The National Association of Independent Colleges and Universities, COGR. (Attachments: # 1 Proposed Brief of Amici Curiae)(Bueker, John) (Entered: 04/17/2025)	
80	04/17/2025	Amicus Curiae APPEARANCE entered by John P. Bueker on behalf of The Association of American Medical Colleges, The American Association of State Colleges and Universities, The American Council on Education, The Association of American Universities, The Association of Governing Boards of Universities and Colleges, The Association of Public and Land-Grant Universities, The National Association of Independent Colleges and Universities, COGR. (Bueker, John) (Entered: 04/17/2025)	
81	04/17/2025	Amicus Curiae APPEARANCE entered by Douglas Hallward-Driemeier on behalf of The Association of American Medical Colleges, The American Association of State Colleges and Universities, The American Council on Education, The Association of American Universities, The Association of Governing Boards of Universities and Colleges, The Association of Public and Land-Grant Universities, The National Association of Independent Colleges and Universities, COGR. (Hallward-Driemeier, Douglas) (Entered: 04/17/2025)	
82	04/17/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Stephanie A. Webster Filing fee: $ 125, receipt number AMADC-10959319 by The Association of American Medical Colleges, The American Association of State Colleges and Universities, The American Council on Education, The Association of American Universities, The Association of Governing Boards of Universities and Colleges, The Association of Public and Land-Grant Universities, The National Association of Independent Colleges and Universities, COGR.(Bueker, John) (Entered: 04/17/2025)	
83	04/17/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Amish A. Shah Filing fee: $ 125, receipt number AMADC-10959604 by The Association of American Medical Colleges, The American Council on Education, The Association of American Universities, The Association of Governing Boards of Universities and Colleges, The Association of Public and Land-Grant Universities, The National Association of Independent Colleges and Universities, COGR.(Bueker, John) (Entered: 04/17/2025)	
84	04/18/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 79 Motion for Leave to File Amici Curiae Brief ; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (MBM) (Entered: 04/18/2025)	
85	04/18/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 82 Motion for Leave to Appear Pro Hac Vice Added Stephanie A. Webster. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to	

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		upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MBM) (Entered: 04/18/2025)	
86	04/18/2025	AMICUS BRIEF filed by The Association of American Medical Colleges (AAMC), The American Association of State Colleges and Universities (AASCU), The American Council on Education (ACE), The Association of American Universities (AAU), The Association of Governing Boards of Universities and Colleges (AGB), The Association of Public and Land-Grant Universities (APLU), COGR, The National Association of Independent Colleges and Universities (NAICU) . (Bueker, John) (Entered: 04/18/2025)	
87	04/18/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 83 Motion for Leave to Appear Pro Hac Vice Added Amish A. Shah. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected.Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 04/18/2025)	
88	04/18/2025	Amicus Curiae APPEARANCE entered by Stephanie A. Webster on behalf of The Association of American Medical Colleges (AAMC), The American Association of State Colleges and Universities (AASCU), The American Council on Education (ACE), The Association of American Universities (AAU), The Association of Governing Boards of Universities and Colleges (AGB), The Association of Public and Land-Grant Universities (APLU), COGR, The National Association of Independent Colleges and Universities (NAICU). (Webster, Stephanie) (Entered: 04/18/2025)	
89	04/18/2025	Amicus Curiae APPEARANCE entered by Amish Aajay Shah on behalf of The Association of American Medical Colleges (AAMC), The American Association of State Colleges and Universities (AASCU), The American Council on Education (ACE), The Association of American Universities (AAU), The Association of Governing Boards of Universities and Colleges (AGB), The Association of Public and Land-Grant Universities (APLU), COGR, The National Association of Independent Colleges and Universities (NAICU). (Shah, Amish) (Entered: 04/18/2025)	
90	04/22/2025	NOTICE of Appearance by Ketakee Rajiv Kane on behalf of State of California (Kane, Ketakee) (Entered: 04/22/2025)	
91	04/24/2025	NOTICE of Appearance by Lynn Kristine Lodahl on behalf of State of Wisconsin (Lodahl, Lynn) (Entered: 04/24/2025)	
92	04/28/2025	NOTICE of Appearance by Astrid Carrete on behalf of State of New Mexico (Carrete, Astrid) (Entered: 04/28/2025)	
93	04/28/2025	NOTICE of Appearance by Astrid Carrete on behalf of State of New Mexico (Carrete, Astrid) (Entered: 04/28/2025)	
94	04/28/2025	NOTICE of Appearance by Andrew R.W. Hughes on behalf of State of Washington (Hughes, Andrew) (Entered: 04/28/2025)	
95	05/01/2025	Opposition re 76 MOTION for Preliminary Injunction filed by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative	

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		Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services. (Attachments: # 1 Exhibit A - Examples of active, not terminated grants)(Ports, Thomas) (Entered: 05/01/2025)	
96	05/01/2025	Consent MOTION for Extension of Time to May 1, 2025 to file opposition by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services.(Ports, Thomas) (Entered: 05/01/2025)	
97	05/01/2025	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 96 Consent MOTION for Extension of Time to May 1, 2025 to file opposition. (MBM) (Entered: 05/01/2025)	
98	05/01/2025	Judge Brian E. Murphy: ELECTRONIC ORDER OF RECUSAL - In accordance with 28 U.S.C. 455(a), I hereby recuse myself from this proceeding. The Clerk is directed to return the case for reassignment.Associated Cases: 1:25-cv-10814-BEM, 1:25-cv-10787-BEM(BIB) (Entered: 05/01/2025)	
99	05/01/2025	ELECTRONIC NOTICE of Reassignment. Judge William G. Young added. Judge Brian E. Murphy no longer assigned to case. (CM) (Entered: 05/01/2025)	
100	05/02/2025	ELECTRONIC NOTICE Resetting Hearing on Motion 76 MOTION for Preliminary Injunction : Motion Hearing reset for 5/8/2025 11:30 AM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders	

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		and public notices of the Court available on www.mad.uscourts.gov or contact the session here.(KB) (Entered: 05/02/2025)	
101	05/05/2025	REPLY to Response to 76 MOTION for Preliminary Injunction filed by Commonwealth of Massachusetts, State of Arizona, State of California, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin. (Attachments: # 1 Exhibit 1 (Declaration of Joshua Fessel), # 2 Exhibit 2 (Supp. Declaration of Ryan Hutchings), # 3 Exhibit 3 (Second Supp. Declaration of Jeremy M. Berg), # 4 Exhibit 4 (Supp. Declaration of Theresa A. Maldonado), # 5 Exhibit 5 (Declaration of Annika Barber))(Cedrone, Gerard) (Entered: 05/05/2025)	
102	05/06/2025	NOTICE of Appearance by Kathleen Boergers on behalf of State of California (Boergers, Kathleen) (Entered: 05/06/2025)	
103	05/07/2025	Notice of Supplemental Authorities re 76 MOTION for Preliminary Injunction (Attachments: # 1 Exhibit A - Decision in Rhode Island v. Trump)(Cedrone, Gerard) (Entered: 05/07/2025)	
104	05/08/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Motion Hearing held on 5/8/2025 re 76 MOTION for Preliminary Injunction. Court hears argument on subject matter jurisdiction. Court takes the matter under advisement. If the Court determines it does have subject matter jurisdiction it will hold a case management conference May 13, 2025 at 2:00pm. Court requests plaintiffs to submit spreadsheet as discussed at the hearing by Tuesday, May 13th. Case Management Conference set for 5/13/2025 02:00 PM in Courtroom 18 (In person only with Remote Access Provided) before Judge William G. Young.). In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here.(Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Gerard J. Cedrone, Chris Pappavaselio, Katherine B. Dirks, Rachel M. Brown, Vanessa Azniv Arslanian, and Sophia TonNu for plaintiffs and Thomas Ports, Jr, and Anuj K. Khetarpal for defendants) (KB) (Entered: 05/08/2025)	
105	05/12/2025	Judge William G. Young: ORDER entered. MEMORANDUM AND ORDER ON SUBJECT MATTER JURISDICTION (Sonnenberg, Elizabeth) (Entered: 05/12/2025)	
106	05/12/2025	ELECTRONIC NOTICE of Hearing. Case Management Conference set for 5/13/2025 02:00 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here. (KB) (Entered: 05/12/2025)	
107	05/12/2025	Transcript of Preliminary Injunction held on May 8, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at	

#	Date	Proceeding Text	Source
		rhr3tubas@aol.com. Redaction Request due 6/2/2025. Redacted Transcript Deadline set for 6/12/2025. Release of Transcript Restriction set for 8/11/2025. (DRK) (Entered: 05/12/2025)	
108	05/12/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm (DRK) (Entered: 05/12/2025)	
109	05/13/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Case Management Conference held on 5/13/2025. Court discusses next steps for the case. Court hears from the parties. The first portion of the case will focus on termination of grants. The defendants to file administrative records by June 2, 2025. Parties may file briefs. The Court sets a further hearing June 16, 2025 at 10:00am. The parties shall inform the Court if the June 16th hearing will be on the record submitted or if there is a dispute about whether evidence should be entered at the hearing. On the unreasonable delay issue the parties shall propose schedule(s) on this issue and the Court will set a further status conference on it. <Hearing set for 6/16/2025 10:00 AM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here.(Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Katherine Dirks, Rachel Brown, Daniel Ambar for the plaintiffs and Thomas Ports, Jr. and Anuj Khetarpal for the defendants) (KB) (Entered: 05/14/2025)	
110	05/16/2025	Transcript of Case Management Conference held on May 13, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 6/6/2025. Redacted Transcript Deadline set for 6/16/2025. Release of Transcript Restriction set for 8/14/2025. (DRK) (Entered: 05/19/2025)	
111	05/16/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm (DRK) (Entered: 05/19/2025)	
112	05/23/2025	ELECTRONIC NOTICE of Hearing. Status Conference re case management of related cases set for 6/3/2025 11:00 AM in Courtroom 18 (In person only) before Judge William G. Young. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here.Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 05/23/2025)	

#	Date	Proceeding Text	Source
113	05/29/2025	JOINT STATEMENT of counsel regarding schedule for further proceedings. (Cedrone, Gerard) (Entered: 05/29/2025)	
114	05/30/2025	NOTICE of Appearance by Phoebe Lockhart on behalf of Commonwealth of Massachusetts (Lockhart, Phoebe) (Entered: 05/30/2025)	
115	06/02/2025	NOTICE of Appearance by Vanessa L Kassab on behalf of State of Delaware (Kassab, Vanessa) (Entered: 06/02/2025)	
116	06/02/2025	MOTION for Leave to Appear Pro Hac Vice for admission of Ian R. Liston Filing fee: $ 125, receipt number AMADC-11043181 by State of Delaware. (Attachments: # 1 Certificate of Ian R. Liston)(Brown, Rachel) (Entered: 06/02/2025)	
117	06/02/2025	Judge William G. Young: ELECTRONIC ORDER entered granting 116 Motion for Leave to Appear Pro Hac Vice Added Ian R. Liston. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MAP) (Entered: 06/02/2025)	
118	06/02/2025	NOTICE of Production of Administrative Record by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services (Attachments: # 1 Certification of Administrative Record)(Khetarpal, Anuj) (Entered: 06/02/2025)	
119	06/03/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Status Conference held on 6/3/2025. Government has produced administrative record in both cases. The Court hears from parties in both cases regarding schedule and June 16th hearing. Court will hear argument on Phase 1 from 10am-1pm on June 16th in both cases. The Court adopts the proposed schedule filed in 25-cv-10814 Document 113 at page 2. The Court modifies the proposed schedule at page 4 as follows: By June 20, 2025, defendants may move to dismiss plaintiffs' claims related to alleged reasonable delay. By July 9, 2025, defendants must lodge the administrative record. Court and parties discuss phase II. Record to be supplemented as to the challenged directives as directed by the Court. If the case(s) were to resolve the parties shall inform the Clerk. (Court Reporter:	

#	Date	Proceeding Text	Source
		Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Kenneth Parreno, Jessie Rossman, Olga Akselrod, Suzanne Schlossberg, Gerard Cedrone, Katherine Dirks, Phoebe Lockhart for plaintiffs and Anuj Khetarpal and Thomas Ports, Jr. for defendants) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/04/2025)	
120	06/04/2025	NOTICE of Appearance by Ian Liston on behalf of State of Delaware (Liston, Ian) (Entered: 06/04/2025)	
121	06/05/2025	Transcript of Status Conference held on June 3, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 6/26/2025. Redacted Transcript Deadline set for 7/7/2025. Release of Transcript Restriction set for 9/3/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 06/05/2025)	
122	06/05/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(DRK) (Entered: 06/05/2025)	
123	06/05/2025	STIPULATION Regarding Phase One Schedule Modifications by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin. (Cedrone, Gerard) (Entered: 06/05/2025)	
124	06/09/2025	MOTION To Complete the Administrative Record by State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin.(Brown, Rachel) (Entered: 06/09/2025)	
125	06/09/2025	TRIAL BRIEF by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human	

#	Date	Proceeding Text	Source
		Services. (Ports, Thomas) (Entered: 06/09/2025)	
126	06/09/2025	MEMORANDUM OF LAW by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin. (Cedrone, Gerard) (Entered: 06/09/2025)	
127	06/09/2025	APPENDIX/EXHIBIT re 126 Memorandum of Law, Proposed Order, Declaration, and Permanent Injunction by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin. (Cedrone, Gerard) (Entered: 06/09/2025)	
128	06/10/2025	Judge William G. Young: ELECTRONIC ORDER entered allowed 124 MOTION To Complete the Administrative Record (MAP) (Entered: 06/10/2025)	
129	06/10/2025	NOTICE by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin regarding the June 16 Hearing (Cedrone, Gerard) (Entered: 06/10/2025)	
130	06/11/2025	ELECTRONIC NOTICE of Hearing. Final Pretrial Conference set for 6/12/2025 11:00 AM in Courtroom 18 (Remote only) before Judge William G. Young. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/11/2025)	
131	06/11/2025	Certification of the Administrative Record (Updated) by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services re 118 Notice (Other),,,,,, (Attachments: # 1 Email, # 2 Certification, # 3 Ex A to certification, # 4 Ex B to certification, # 5 Ex C to certification, # 6 NIH_GRANTS_003825-3910, # 7 NIH_GRANTS_003911-3995, # 8 NIH_GRANTS_003996-4081, # 9 NIH_GRANTS_004082-4165, # 10 NIH_GRANTS_004166-4251, # 11 NIH_GRANTS_004252, # 12 NIH_GRANTS_004253-54, # 13 NIH_GRANTS_004255-57, # 14 NIH_GRANTS_004258-	

#	Date	Proceeding Text	Source
		69, # 15 NIH_GRANTS_004270)(Ports, Thomas) Modified on 6/11/2025 (MAP). (Entered: 06/11/2025)	
132	06/12/2025	Opposition re 124 MOTION To Complete the Administrative Record filed by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services. (Attachments: # 1 Exhibit)(Khetarpal, Anuj) (Entered: 06/12/2025)	
133	06/12/2025	Judge William G. Young: ELECTRONIC ORDER entered vacating 128 Order on 124 Motion to Complete Administrative Record. Motion allowed in part and denied in part as follows: A. Grants not terminated- Denied as moot B. Termination forms- Allowed. "Guidance" is not "deliberation." C. HHS and DOGE imput: Denied on the representation that such search has been made. D. AI Use: Allowed. E. Metadata: Denied without prejudice to seeking such discovery beyond the APA claims. F. Certification. Denied as moot. SO ORDERED(KB) (Entered: 06/12/2025)	
136	06/12/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Final Pretrial Conference held on 6/12/2025. Court and the parties discuss the record in the case. Court has administrative record as it has been provided. Plaintiffs have also filed records. Court hears parties on the matter. Court will review defendants' opposition to the motions to Complete Record. Court will hear oral argument on phase 1 of the case on Monday, June 16th at 10am. Each side will have one hour for argument (plaintiffs in both cases will have one hour combined). Parties to discuss proposed phase 2 schedule on Monday. Court has off the record portion of hearing regarding possibility of settlement. If the case were to settle in part or in whole the parties shall inform the Clerk. (Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Matthew Brinckerhoff, Jessie Rossman, Lisa Mankofsky, Max Roller Selver, Olga Akselrod, Rachel Anne Meeropol, Sydney Kathryn Zazzaro, Gerard Cedrone, Christopher Pappavaselio, Phoebe Lockhart, Rachel Brown, Vanessa Azniv Arslanian, Nimrod Pitsker Elias, Astrid Carrete, Jordan Broadbent for plaintiffs and Anuj Khetarpal and Thomas Ports, Jr. for defendants) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/13/2025)	
134	06/13/2025	TRIAL BRIEF in Response to Plaintiffs' Opening Briefs by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International	

#	Date	Proceeding Text	Source
		Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services. (Ports, Thomas) (Entered: 06/13/2025)	
135	06/13/2025	MEMORANDUM OF LAW by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin to 125 Trial Brief,,,,,. (Attachments: # 1 Appendix A - Plaintiffs' Response to Defendants' Identification of Grants)(Cedrone, Gerard) (Entered: 06/13/2025)	
137	06/13/2025	Transcript of Final Pretrial held on June 12, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 7/7/2025. Redacted Transcript Deadline set for 7/14/2025. Release of Transcript Restriction set for 9/11/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 06/13/2025)	
138	06/13/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(DRK) (Entered: 06/13/2025)	
139	06/13/2025	NOTICE by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of	

#	Date	Proceeding Text	Source
		General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services of Production of Administrative Record (Attachments: # 1 Designation and Certification of Administrative Record)(Khetarpal, Anuj) (Entered: 06/13/2025)	
140	06/15/2025	Joint MOTION for Protective Order by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin.(Cedrone, Gerard) (Entered: 06/15/2025)	
141	06/16/2025	ELECTRONIC NOTICE of Hearing. Hearing set for 6/16/2025 at 2:00pm. (In person with remote access provided) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/16/2025)	
142	06/16/2025	Judge William G. Young: STIPULATED PROTECTIVE ORDER entered. Granting (140) Joint Motion for Protective Order in case 1:25-cv-10814-WGY Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(KB) (Entered: 06/16/2025)	
143	06/16/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Bench Trial as to Phase 1 held on 6/16/2025.Court hears argument on Phase 1 of the case. Defendants ask Court to take Judicial Notice of the Federal Register Notices. Court takes Judicial Notice. Defendants move to admit into evidence 13 Certified records. No objection. Admitted as exhibit 1. Court takes the matter under advisement. Parties will inform the Court if they wish for the Court to reconvene in the afternoon or if they wish for the Court to hold off issuing a ruling as to Phase 1. The Court reconvenes in the afternoon. The Court announces the findings and rulings that it is able to make today. The challenged directives are vacated. A written order will issue. Defendants shall promptly comply with the order of the Court. Plaintiffs to submit a proposed partial but final judgment as to Phase 1 by June 17, 2025. The Court discusses evidence as to harm. The parties will meet and inform the Court if an evidentiary hearing regarding harm is necessary. (Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Kenneth Parreno, Jessie Rossman, Olga Akselrod, Rachel Anne Meeropol, Gerard Cedrone, Rachel Brown, Nimrod Pitsker Elias for plaintiffs and Anuj Khetarpal and Thomas Ports, Jr. for defendants) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/17/2025)	
144	06/17/2025	Proposed Document(s) submitted by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin. Document received: Proposed Rule 54(b) Final Judgment. (Cedrone, Gerard) (Entered: 06/17/2025)	
145	06/18/2025	ELECTRONIC NOTICE of Hearing. Status Conference set for 6/18/2025 02:00 PM in Courtroom 18 (Remote only) before Judge William G. Young. This hearing will be conducted by video	

#	Date	Proceeding Text	Source
		conference. Counsel of record will receive a video conference invite at the email registered in CM/ECF. If you have technical or compatibility issues with the technology, please notify the courtroom deputy of the session as soon as possible.Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here.Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/18/2025)	
146	06/18/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Status Conference re proposed judgments held on 6/18/2025. The Court hears from parties regarding proposed judgments and modifies judgments as stated. Plaintiffs' counsel shall re-submit the proposed judgments as modified by the Court. (Attorneys present: Olga Akselrod, Lisa Mankofsky, Suzanne Schlossberg, Jessie J. Rossman, Gerard Cedrone, Chris Pappavaselio, Phoebe Lockhart, Rachel M. Brown for plaintiffs and Anuj Khetarpal and Thomas Ports, Jr. for defendants)(Court Reporter: Richard Romanow at rhr3tubas@aol.com.) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 06/18/2025)	
147	06/18/2025	Proposed Document(s) submitted by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin. Document received: Proposed Rule 54(b) Final Judgment (Revised per Court's Instructions). (Attachments: # 1 Exhibit A - Spreadsheet)(Cedrone, Gerard) (Entered: 06/18/2025)	
148	06/20/2025	MOTION to Dismiss and to set an expedited response deadline of June 26 by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services. (Ports, Thomas) Modified on 6/22/2025 (MAP). (Entered: 06/20/2025)	
149	06/20/2025	Opposition re 148 MOTION to Dismiss and to set an expedited	

#	Date	Proceeding Text	Source
		response deadline of June 26 (Opposition as to Motion to Expedite) filed by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin. (Cedrone, Gerard) (Entered: 06/20/2025)	
150	06/22/2025	MEMORANDUM in Support re 148 MOTION to Dismiss and to set an expedited response deadline of June 26 filed by Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services. (MAP) (Entered: 06/22/2025)	
151	06/23/2025	Judge William G. Young: WGY RULE 54(b) FINAL JUDGMENT (Sonnenberg, Elizabeth) (Additional attachment(s) added on 6/23/2025: # 1 List of Grants) (MAP). (Main Document 151 replaced on 6/23/2025) (MAP). (Entered: 06/23/2025)	
152	06/23/2025	NOTICE OF APPEAL as to 105 Memorandum & ORDER, 151 Order by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human	

#	Date	Proceeding Text	Source
		Services. Fee Status: US Government. NOTICE TO COUNSEL: A Transcript Report/Order Form, which can be downloaded from the First Circuit Court of Appeals web site at http://www.ca1.uscourts.gov MUST be completed and submitted to the Court of Appeals. Counsel shall register for a First Circuit CM/ECF Appellate Filer Account at http://pacer.psc.uscourts.gov/cmecf. Counsel shall also review the First Circuit requirements for electronic filing by visiting the CM/ECF Information section at http://www.ca1.uscourts.gov/cmecf. US District Court Clerk to deliver official record to Court of Appeals by 7/14/2025. (Ports, Thomas) (Entered: 06/23/2025)	
153	06/23/2025	MOTION to Stay Pending Appeal by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services.(Ports, Thomas) (Entered: 06/23/2025)	
154	06/23/2025	MEMORANDUM in Support re 153 MOTION to Stay Pending Appeal filed by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services. (Ports, Thomas) (Entered: 06/23/2025)	

#	Date	Proceeding Text	Source
155	06/23/2025	Certified and Transmitted Abbreviated Electronic Record on Appeal to US Court of Appeals re 152 Notice of Appeal. (MAP) (Entered: 06/23/2025)	
156	06/23/2025	Transcript of Bench Trial, Phase 1 (Closings) held on June 16, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 7/14/2025. Redacted Transcript Deadline set for 7/24/2025. Release of Transcript Restriction set for 9/22/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 06/24/2025)	
157	06/23/2025	Transcript of Status Conference held on June 18, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 7/14/2025. Redacted Transcript Deadline set for 7/24/2025. Release of Transcript Restriction set for 9/22/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 06/24/2025)	
158	06/23/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 06/24/2025)	
159	06/24/2025	USCA Case Number 25-1612 for 152 Notice of Appeal, filed by National Institutes of Health, National Institute on Aging, Jayanta Bhattacharya, National Institute on Minority Health and Health Disparities, United States Department of Health and Human Services, National Institute of Mental Health, National Eye Institute, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute on Drug Abuse, National Institute of Diabetes and Digestive and Kidney Diseases, National Center for Advancing Translational Sciences, National Cancer Institute, National Heart, Lung, and Blood Institute, National Institute of Environmental Health Sciences, National Center for Complementary and Integrative Health, National Library of Medicine, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute of Nursing Research, National Institute of Neurological Disorders and Stroke, National Institute of General Medical Sciences, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., National Institute on Deafness and Other Communication Disorders, National Institute of Biomedical Imaging and Bioengineering, NIH Center for Scientific Review, National Human Genome Research Institute, National Institute of Dental and Craniofacial Research, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases. (MAP) (Entered: 06/24/2025)	
160	06/24/2025	Judge William G. Young: ORDER entered. (Sonnenberg, Elizabeth) (Entered: 06/24/2025)	
161	06/24/2025	Supplemental Record on Appeal transmitted to US Court of Appeals re 152 Notice of Appeal Documents included: ECF No. 160 (MAP) (Entered: 06/24/2025)	
162	06/30/2025	Opposition re 148 MOTION to Dismiss and to set an expedited response deadline of June 26 filed by Commonwealth of Massachusetts, State of Arizona, State of California, State of	

#	Date	Proceeding Text	Source
		Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin. (Attachments: # 1 Exhibit A - Supplemental Declaration of Ryan Hutchings, # 2 Exhibit B - Supplemental Declaration of Jeremy M. Berg)(Cedrone, Gerard) (Entered: 06/30/2025)	
163	07/02/2025	Judge William G. Young: ORDER entered. FINDINGS OF FACT, RULINGS OF LAW, AND ORDER FOR PARTIAL SEPARATE AND FINAL JUDGMENTAssociated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(Sonnenberg, Elizabeth) (Entered: 07/02/2025)	
164	07/07/2025	Supplemental Record on Appeal transmitted to US Court of Appeals re 152 Notice of Appeal. (MAP) (Entered: 07/07/2025)	
165	07/09/2025	NOTICE by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services Notice of Production of Phase Two ARs (Attachments: # 1 Designation and Certification of the Administrative Records)(Ports, Thomas) (Entered: 07/09/2025)	
166	07/11/2025	NOTICE of Appearance by Nadav S. Pearl on behalf of Commonwealth of Massachusetts (Pearl, Nadav) (Entered: 07/11/2025)	
167	07/17/2025	NOTICE of Appearance by Samuel Hobbs on behalf of Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute	

#	Date	Proceeding Text	Source
		on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services (Hobbs, Samuel) (Entered: 07/17/2025)	
168	07/18/2025	OPINION of USCA as to 152 Notice of Appeal, filed by National Institutes of Health, National Institute on Aging, Jayanta Bhattacharya, National Institute on Minority Health and Health Disparities, United States Department of Health and Human Services, National Institute of Mental Health, National Eye Institute, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute on Drug Abuse, National Institute of Diabetes and Digestive and Kidney Diseases, National Center for Advancing Translational Sciences, National Cancer Institute, National Heart, Lung, and Blood Institute, National Institute of Environmental Health Sciences, National Center for Complementary and Integrative Health, National Library of Medicine, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute of Nursing Research, National Institute of Neurological Disorders and Stroke, National Institute of General Medical Sciences, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., National Institute on Deafness and Other Communication Disorders, National Institute of Biomedical Imaging and Bioengineering, NIH Center for Scientific Review, National Human Genome Research Institute, National Institute of Dental and Craniofacial Research, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases. The Department's Motion for a Stay is DENIED. (MAP) (Entered: 07/20/2025)	
169	07/18/2025	ORDER of USCA as to 152 Notice of Appeal, filed by National Institutes of Health, National Institute on Aging, Jayanta Bhattacharya, National Institute on Minority Health and Health Disparities, United States Department of Health and Human Services, National Institute of Mental Health, National Eye Institute, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute on Drug Abuse, National Institute of Diabetes and Digestive and Kidney Diseases, National Center for Advancing Translational Sciences, National Cancer Institute, National Heart, Lung, and Blood Institute, National Institute of Environmental Health Sciences, National Center for Complementary and Integrative Health, National Library of Medicine, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute of Nursing Research, National Institute of Neurological Disorders and Stroke, National Institute of General Medical Sciences, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., National Institute on Deafness and Other Communication Disorders, National Institute of Biomedical Imaging and Bioengineering, NIH Center for Scientific Review, National Human Genome Research Institute, National Institute of Dental and Craniofacial Research, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases (MAP) (Entered: 07/20/2025)	
170	07/22/2025	ELECTRONIC NOTICE of Hearing. Status Conference set for 7/28/2025 11:00 AM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 07/22/2025)	

#	Date	Proceeding Text	Source
171	07/23/2025	MOTION for Discovery and to Set a Phase Two Case Schedule and Trial Date by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin.(Cedrone, Gerard) (Additional attachment(s) added on 7/24/2025: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F) (MAP). (Main Document 171 replaced on 7/24/2025) (MAP). (Entered: 07/23/2025)	
172	07/28/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Status Conference held on 7/28/2025. Parties discuss status of case and phase II. Court adopts schedule but modifies pretrial and bench trial date. Final Pretrial Conference set for September 2, 2025 at 10:00 AM. The Court will hear argument on motion to dismiss at the final pretrial conference. The Bench trial will occur no later than September 15, 2025. Court hears the parties on discovery. Court takes the legal arguments as to discovery under advisement. Court will issue an order on or after August 15th. Court hears parties on defendants' stipulation as to supplemental claims. If Court requires more data the Court will order it at that time, the stipulation may be sufficient. Court discusses application for stay in the Supreme Court and possible outcomes. Final Pretrial Conference set for 9/2/2025 10:00 AM in Courtroom 18 (In person only with Remote Access Provided) before Judge William G. Young. Bench Trial set for 9/15/2025 09:00 AM in Courtroom 18 (In person only with Remote Access Provided) before Judge William G. Young.(Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Max Roller Selver, Suzanne Schlossberg, Katherine B. Dirks, Phoebe Lockhart, Anuj K. Khetarpal and Samuel Hobbs) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 07/29/2025)	
173	07/30/2025	Transcript of Status Conference held on July 28, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 8/20/2025. Redacted Transcript Deadline set for 9/2/2025. Release of Transcript Restriction set for 10/28/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY (DRK) (Entered: 07/30/2025)	
174	07/30/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(DRK) (Entered: 07/30/2025)	
175	07/30/2025	Opposition re 171 MOTION for Discovery and to Set a Phase Two Case Schedule and Trial Date filed by Jayanta Bhattacharya, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy	

#	Date	Proceeding Text	Source
		and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services. (Khetarpal, Anuj) (Entered: 07/30/2025)	
176	08/15/2025	MEMORANDUM OF LAW by Jayanta Bhattacharya, COGR, Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center for Advanced Study in the Health Sciences, Robert F. Kennedy, Jr., NIH Center for Scientific Review, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health and Health Disparities, National Institutes of Health, National Library of Medicine, United States Department of Health and Human Services. (Khetarpal, Anuj) (Entered: 08/15/2025)	
177	08/21/2025	NOTICE of Appearance by Leanne E. Hartmann on behalf of State of Oregon (Hartmann, Leanne) (Entered: 08/21/2025)	
178	08/22/2025	NOTICE of Withdrawal of Appearance by Chris Pappavaselio (Pappavaselio, Chris) (Entered: 08/22/2025)	
179	08/25/2025	NOTICE of Appearance by Eric A. Martignetti on behalf of Commonwealth of Massachusetts (Martignetti, Eric) (Entered: 08/25/2025)	
180	08/25/2025	STIPULATION re 171 MOTION for Discovery and to Set a Phase Two Case Schedule and Trial Date -- Joint Stipulation on Introduction of Evidence at Trial, Discovery, and Administrative Record for Phase Two by Commonwealth of Massachusetts, State of Arizona, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Maryland, State of Minnesota, State of Nevada, State of New Jersey, State of New Mexico, State of New York, State of Oregon, State of Rhode Island, State of Washington, State of Wisconsin. (Cedrone, Gerard) (Entered: 08/25/2025)	
181	08/29/2025	NOTICE OF COURTROOM CHANGE: The hearing on 9/2/2025 will occur in Courtroom 17. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 08/29/2025)	

#	Date	Proceeding Text	Source
182	09/02/2025	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Final Pretrial Conference held on 9/2/2025. Court addresses Supreme Court order. Court takes recess for parties to confer. Court continues hearing until Thursday at 10:00AM. Pretrial deadlines are extended accordingly. Final Pretrial Conference set for 9/4/2025 10:00 AM in Courtroom 10 (In person with remote access provided) before Judge William G. Young. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here. (Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: Kenneth Parreno, Alejandro Ortiz, Jessie J. Rossman, Olga Akselrod, Gerard J. Cedrone, Phoebe Lockhart, Vanessa Azniv Arslanian for plaintiffs and Samuel Hobbs and Anuj Khetarpal for defendants) Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/02/2025)	
183	09/03/2025	ELECTRONIC NOTICE OF RESCHEDULING: At request of the parties the Final Pretrial Conference is reset for 9/9/2025 03:30 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Bench trial is reset for 9/22/2025. Deadlines are extended accordingly. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html.For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here.Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/03/2025)	
184	09/04/2025	Transcript of Final Pretrial Conference held on September 2, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 9/25/2025. Redacted Transcript Deadline set for 10/6/2025. Release of Transcript Restriction set for 12/3/2025. Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(DRK) (Entered: 09/04/2025)	
185	09/04/2025	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm Associated Cases: 1:25-cv-10814-WGY, 1:25-cv-10787-WGY(DRK) (Entered: 09/04/2025)	
186	09/08/2025	ELECTRONIC NOTICE OF RESCHEDULING: At request of the parties, the Final Pretrial Conference is reset for 9/18/2025 02:00 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Bench Trial is reset for 10/6/2025 09:00 AM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/08/2025)	
187	09/17/2025	ELECTRONIC NOTICE Canceling Hearing. Due to a conflict in the Court's schedule the Final Pretrial Conference set for	

#	Date	Proceeding Text	Source
		9/18/2025 is cancelled and will be rescheduled. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/17/2025)	
188	09/18/2025	ELECTRONIC NOTICE OF RESCHEDULING: At request of the parties, the Final Pretrial Conference is reset for 9/30/2025 02:00 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Bench Trial tentatively reset for 10/14/2025 09:00 AM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Final Pretrial Conference set for 9/30/2025 02:00 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/18/2025)	
189	09/25/2025	ELECTRONIC NOTICE Cancelling Hearings. The Final Pretrial Conference set for 9/30/2025 and the Bench Trial set for 10/14/2025 are cancelled and will be rescheduled for dates to be determined. Associated Cases: 1:25-cv-10787-WGY, 1:25-cv-10814-WGY(KB) (Entered: 09/25/2025)	

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; and NICOLE MAPHIS *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, *in his official capacity as Director of the National Institutes of Health*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*, *Defendants*.	Case No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. The National Institutes of Health ("NIH") is the world's leading funder of biomedical and behavioral research, responsible for the discovery of new ways to diagnose, prevent, and treat the most challenging diseases including cancer, strokes, diabetes, and Alzheimer's disease. Long considered "the crown jewel" of the federal government, NIH has

funded research that has led to more than 100 Nobel Prizes and has supported more than 99 percent of the drugs approved by federal regulators from 2010 to 2019.[1]

2. In late February 2025, Defendants upended NIH's enviable track record of rigor and excellence, launching a reckless and illegal purge to stamp out NIH-funded research that addresses topics and populations that they disfavor. Plaintiffs, who are leading health research organizations and research scientists, bring this case because they have been harmed by Defendants' unlawful grant terminations and midstream abandonment of grant application processes.

3. Congress created NIH nearly 100 years ago and funds it through annual appropriations so that it can "improve health, revolutionize science, and serve society."[2] Congress has provided additional directives to NIH to ensure that its research accrues to the benefit of all Americans.

4. NIH has carried out Congress's purpose and achieved its legendary successes through directing most of its budget to thousands of researchers at universities, medical schools, and other institutions in all 50 states. For decades, NIH has been guided by congressional mandate, regulatory requirements, and scientific expertise when determining what research to prioritize and fund. NIH also is subject to the Administrative Procedure Act's ("APA") requirement of reasoned decision-making, which it effectuates through rigorous grounding in scientific evidence. Pursuant to a congressional mandate, NIH develops and publishes a five-year Strategic Plan to direct its

[1] *See Nobel Laureates*, Nat'l Insts. of Health, (Oct. 9, 2024) https://www.nih.gov/about-nih/what-we-do/nih-almanac/nobel-laureates; E. Galkina Cleary et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4 JAMA Health Forum e230511 (2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378.
[2] *Impact of NIH Research*, Nat'l Insts. of Health, https://www.nih.gov/about-nih/what-we-do/impact-nih-research.

priorities, "focused on science and good stewardship of research, guided by evidence, and informed by NIH's many stakeholders."[3]

5. Under this legally established framework, thousands of researchers across the country regularly apply for NIH grants to fund their research. NIH makes grant decisions following a highly competitive and rigorous process involving layers of expert scientific review over many months. Consequently, for decades, terminations of ongoing NIH grants have been exceedingly rare.

6. This all changed beginning in February of 2025, when Defendants issued a series of directives to terminate large numbers of grants and to refuse to consider certain categories of pending grant applications ("the Directives"). These Directives conflict with constitutional, statutory, and regulatory requirements. When issuing termination letters pursuant to the Directives, NIH has not referenced or met any of the standards in its governing statute or regulations. In fact, the sole legal basis that NIH cited for its authority to terminate the grants is inapplicable. It has not highlighted any genuine concerns with the rigor of projects or any underlying data; in a matter of weeks it has just declared them all "unscientific." More broadly, it has parroted the generalized and conclusory justification that the cancelled programs "no longer effectuate agency priorities." This is not a proper ground for termination under governing law.

7. As a result of the Directives, hundreds of NIH-funded research projects—many of which have been underway for years, representing millions of hours of work and hundreds of millions of dollars in investment—have been abruptly cancelled without scientifically-valid explanation or cause. Grant application processes have been abandoned midstream and funding opportunities have been removed from NIH's website.

[3] *NIH-Wide Strategic Plan, Fiscal Years 2021–2025*, Nat'l Insts. of Health (July 2021), https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2021-2025-508.pdf at 44.

8. Defendants attempt to justify this ongoing ideological purge of hundreds of critical research projects because they assertedly have some connection to "gender identity" or "Diversity, Equity, and Inclusion" ("DEI") or other vague, now-forbidden language. Indeed, Defendants' campaign against peer-reviewed science has not stopped at topics deemed to be related to gender or DEI. Defendants' ideological purity Directives also seek to cancel research deemed related to "vaccine hesitancy," "COVID," and studies involving entities located in South Africa and China, among other things. Additionally, NIH has stopped considering submitted applications to programs designed to diversify the backgrounds of those in tenure-track positions at research universities. Defendants' actions have been taken in apparent disregard to Congress's express mandate that NIH fund research to address health equity and health disparities, include diverse populations in its studies, improve efforts to study the health of gender and sexual minorities, and enhance diversity in the biomedical research profession.

9. The new arbitrary regime is not codified in any law or policy. The operative NIH Strategic Plan, developed in furtherance of congressional mandate, has been in effect since September 2021, and remains in effect today. Defendants have failed to develop any guidelines, definitions, or explanations to avoid arbitrary and capricious decision-making in determining the parameters of the agency's prohibitions against research with some connection to DEI, gender, and other topics that fail Defendants' ideological conformity screen. Nor do Defendants' actions take into consideration the vast harms they have caused to scientific research and public health.

10. Plaintiffs are individual researchers and organizations whose members are researchers who have secured (or are in the process of securing) funding from NIH. For example, individual Plaintiffs have received NIH grants for research in the areas of Alzheimer's disease, disparities in pregnancy health, violence prevention among children, and the efficacy of

preventative HIV medications. Plaintiffs pursue careers in medical research to help discover new treatments, cure diseases, and improve the health of people and communities across the country.

11. Plaintiffs have already suffered extensive harm from Defendants' unlawful actions, and those with grants that have yet to be cancelled wonder if they are soon to receive another vague, boilerplate termination letter. In just the past few weeks, for example, Plaintiffs and their members are facing the loss of jobs, staff, and income. Patients enrolled in NIH studies led by Plaintiffs face abrupt cancellations of treatment in which they have invested months of time with no explanation or plan for how to mitigate the harm. Over $2.4 billion is at stake just in grants recently purged, including $1.3 billion already spent on projects stopped midstream that is now wasted, and $1.1 billion—that Plaintiffs and others have acted in reliance on—has been revoked. As a result of Defendants' Directives, scientific advancement will be delayed, treatments will go undiscovered, human health will be compromised, and lives will be lost.

12. Plaintiffs request that the Court declare unlawful Defendants' Directives; declare Defendants' termination of grants in this manner unlawful; order Defendants to end their arbitrary and capricious, unconstitutional, and unlawful actions; and order Defendants to restore funding to the terminated NIH grants.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 because this action arises under federal law, including the United States Constitution and the Administrative

Procedure Act ("APA"), 5 U.S.C. §§ 551 *et seq*. This Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to 28 U.S.C. §§ 2201–02 and 5 U.S.C. §§ 705–06.

14. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e)(1)(C) because Defendants are officers and agencies of the United States, no real property is at issue in this case, and one or more Plaintiffs are residents of this District.

PARTIES

A. Plaintiffs

15. Plaintiff Dr. Brittany Charlton is an Associate Professor at Harvard Medical School and Harvard T.H. Chan School of Public Health. She is a resident of Massachusetts and the Founding Director of the LGBTQ Health Center of Excellence, a partnership of the Harvard Pilgrim Health Care Institute and Harvard T.H. Chan School of Public Health. Dr. Charlton is a leading scholar of LGBTQ health inequities, particularly in cancer and reproductive health, and also focuses on contraception use and family planning among people of all sexual orientations and gender identities. She has received continuous funding for her research for the last 15 years from NIH. Since February 2025, Dr. Charlton has had five grants terminated by NIH because each, allegedly, "no longer effectuates agency priorities."

16. Plaintiff Dr. Katie Edwards is a professor at the University of Michigan School of Social Work. Dr. Edwards' research focuses on preventing sexual and related forms of violence among minority communities, using evidence-based, affirming, and culturally-grounded approaches. Her current work is focused on program development and evaluation with Indigenous youth and communities, as well as LGBTQ+ youth and young people. To date, she has published more than 220 peer-reviewed articles, which were made possible, in part, through obtaining millions of dollars in research funding over her career. Since February 2025, NIH has terminated

at least six grants in support of Dr. Edwards' research in projects where she is the principal investigator or co-investigator because, according to NIH, each of these grants "no longer effectuates agency priorities."

17. Plaintiff Dr. Peter Lurie is an experienced research physician and the President and Executive Director of the Center for Science in the Public Interest, a 501(c)(3) nonprofit organization based in Washington, D.C. that advocates for improving public health through science-based policies and promoting scientific integrity. From 2014–17, he was an Associate Commissioner at the Food and Drug Administration, where he worked on the regulation of over-the-counter drugs, among other projects. Additionally, for decades, Dr. Lurie has participated in biomedical research and policy focused on the treatment and prevention of HIV and AIDS. Dr. Lurie was a consultant and advisor on an NIH-funded grant studying the impact of access to preventative HIV drugs that NIH terminated because, according to NIH, it "no longer effectuates agency priorities."

18. Plaintiff Dr. Nicole Maphis is a postdoctoral fellow at the University of New Mexico's School of Medicine. Her research explores how alcohol usage affects the risk of developing Alzheimer's disease. She is the first and only person in her family to graduate college and comes from a low-income background. Dr. Maphis recently sought a grant through a program explicitly created to facilitate the transition of promising postdoctoral researchers from backgrounds underrepresented in the biomedical research workforce into independent, tenure-track or equivalent research-intensive faculty positions. Even though Dr. Maphis satisfies the eligibility criteria for the program and invested months into assembling her application, NIH is refusing to consider Dr. Maphis's grant application solely because the program is designed to help diversify the profession.

19. Founded in 1872, Plaintiff American Public Health Association ("APHA") represents about 50,000 people through organizational and individual memberships and has more than 23,000 individual public health professional members. APHA acts to build capacity in the public health community and champions optimal, equitable health and well-being for all. APHA speaks out for public health issues and policies backed by science. APHA and its members also work to ensure that health services are distributed equitably to all communities and research how disease, injury, or health related issues affect marginalized populations. APHA receives grants from NIH for its *American Journal of Public Health*. In addition, APHA members conduct research that is funded by grants from NIH. APHA has members who have had NIH grants terminated because, according to NIH, each of the grants "no longer effectuates agency priorities." APHA also has members whose grant applications NIH refuses to consider, or who are unable to submit future NIH grant applications due to the uncertainty caused by NIH's actions.

20. Founded in 2002, Plaintiff Ibis Reproductive Health ("Ibis") is a global research organization that drives change through bold, rigorous research and principled partnerships that advance sexual and reproductive autonomy, choice, and health worldwide. With offices in locations including Cambridge, Massachusetts, Ibis has a highly trained and committed staff of demographers, epidemiologists, and public health researchers leading projects with more than 100 partners in 30 countries. Research is core to the organization's work, and the organization's agenda is informed by a principled partnership approach with communities, including transgender and gender diverse community members, to identify key gaps in information and resources concerning reproductive health, autonomy, and health care access for these populations. In September 2023, Ibis was awarded a R01 grant providing about $2.5 million over five years, to study survey design

for diverse populations, including those who identify as transgender or gender diverse. In March 2025, NIH terminated the grant on the basis that it "no longer effectuates agency priorities."

21. The International Union, United Automobile, Aerospace and Agricultural Implement Workers of America ("UAW") is one of the largest and most diverse unions in North America, with members in the United States, Canada and Puerto Rico and in virtually every sector of the economy. From its earliest days, the UAW has been a leader in the struggle to secure economic and social justice for all people. It has a rich history of supporting inclusion, equity, and diversity in the higher education sector and in all workplaces. The UAW has nearly 1,000,000 active and retired members and represents approximately 120,000 workers in higher education—graduate students, postdoctoral scientists, researchers, university staff, and faculty—at institutions across the country including Northeastern University, Wellesley College, University of Southern California, Columbia University, Harvard University, University of Pennsylvania, Princeton University, and Worcester Polytechnic Institute, among many others. Tens of thousands of UAW members rely on NIH grant funding for their jobs and training. These members benefit from all NIH grant and fellowship types and play a variety of roles, including on NIH grant-funded projects as principal investigators. UAW has members whose grants have been cancelled because, according to NIH, each of the grants "no longer effectuates agency priorities." UAW also has members whose grant applications NIH refuses to consider, or who are unable to submit future NIH grant applications due to the uncertainty caused by NIH's actions.

B. Defendants

22. Defendant the National Institutes of Health ("NIH") is an agency of the United States, established pursuant to 42 U.S.C. § 281, and is housed within the United States Department of Health and Human Services.

23. Defendant Jay Bhattacharya is Director of NIH and is sued in his official capacity.

24. Defendant the United States Department of Health and Human Services ("HHS") is an agency of the United States that houses NIH. HHS is a department of the executive branch of the United States.

25. Defendant Robert F. Kennedy, Jr. is the Secretary of HHS and is sued in his official capacity.

FACTUAL ALLEGATIONS

A. Overview of the Structure and Priorities of NIH

1. History of NIH

26. In 1930, Congress enacted the Ransdell Act, establishing a "National Institute of Health" and appropriating funds to the newly-formed institute for the purpose of "ascertaining the cause, prevention, and cure of disease affecting human beings."[4] The Ransdell Act authorized the creation of "fellowships" for "individual scientists."

27. Since then, Congress has repeatedly increased its investment in NIH, including by funding additional Institutes and Centers ("ICs") that operate within NIH.[5]

28. Over these decades of expansion, research funded through NIH has led to medical breakthroughs. For example, NIH-funded research played a critical role in developing numerous lifesaving treatments, including chemotherapy drugs, heart valve transplants, medications for

[4] Ransdell Act, Pub. L. No. 71–251, 46 Stat. 379 (1930) (codified at 42 U.S.C. §§ 21 *et seq*.).
[5] *NIH Budget History*, Nat'l Insts. of Health (Aug. 2024), https://report.nih.gov/nihdatabook/category/1.

managing type 2 diabetes, and a clot-busting medicine that is used as a first-line treatment in stroke patients.[6]

29. Today, NIH is the largest funder of biomedical research in the world, with an operating budget of $48 billion as allocated by Congress. The vast majority—83 percent—is allocated for funding research for institutions and organizations outside of the agency. NIH provides almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state.[7]

2. NIH Structure and Funding

30. NIH is comprised of the Office of the Director, as well as 27 ICs, which span a wide range of functions and focuses. Each of the ICs within NIH serves a particular purpose. For example, Congress established the National Cancer Institute to study and disseminate information about cancer causes, diagnosis, and treatment.

31. Twenty-four of the 27 ICs, as well as several divisions within the Office of the Director, post opportunities for funding for researchers outside of the agency. Congress has also authorized the Director to set aside a portion of NIH's allocated budget for a "Common Fund" dedicated to research that spans across ICs.

32. NIH is primarily funded through congressional appropriations, which includes both funding for agency-wide programs and dedicated budgets for each individual IC.[8] For example, each year, Congress delegates funding directly to the National Institute on Minority Health and Health Disparities to carry out specific legislative purposes, including to "conduct and support []

[6] *Impact of NIH Research: Improving Health*, Nat'l Insts. of Health (Dec. 30, 2024), https://www.nih.gov/about-nih/what-we-do/impact-nih-research/improving-health.
[7] *Budget*, Nat'l Insts. of Health (Oct. 3, 2024), https://www.nih.gov/about-nih/what-we-do/budget#:~:text=Research%20for%20the%20People,%2C%20maintenance%2C%20or%20operational%20costs.
[8] *See* Kavya Sekar, Cong. Research Serv., *NIH Funding FY1996-FY2025,* (June 25, 2024), https://www.congress.gov/crs-product/.

research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities."[9]

33. Congress has also defined mandates on the purposes and aims for which NIH and the ICs must fund research. Four such mandates are of particular relevance here.

34. First, Congress has long mandated that NIH must expend its funds to promote health equity and reduce health disparities across diverse populations. For instance, the Public Service Health Act requires that each IC "utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities."[10] The Minority Health and Health Disparities Research and Education Act of 2000 recognizes the presence of continuing racial disparities "in the burden of illness and death," and obligates NIH to identify and fund health equity research and to establish a center later reclassified as the National Institute on Minority Health and Health Disparities.[11] And the 21st Century Cures Act mandates that NIH consider "disease burden in the United States" and "biological, social, and other determinants of health that contribute to health disparities" in identifying "strategic research priorities and objectives across biomedical research."[12] This statute expressly expands NIH's congressional mandate to study diverse populations and the issues that affect them to encompass the LGBTQ+ population, that "[t]he Director of the National Institutes of Health *shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations*."[13]

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[9] 42 U.S.C. § 285t.
[10] 42 U.S.C. § 282(b)(8)(d)(ii).
[11] Affordable Care Act, Pub. L. No. 111-148, § 1707A(c), 124 Stat. 119, 973 (2010) (codified at 42 U.S.C. §§ 285t–285t-3). *See also* 42 U.S.C. § 285t(b) (National Institute on Minority Health and Health Disparities "shall in expending amounts appropriated under this subpart give priority to conducting and supporting minority health disparities research").
[12] *Id.* at § 282(m)(2)(b)(iii).
[13] 42 U.S.C. § 283p (emphasis added).

35. Second, Congress has also mandated that NIH address the underrepresentation of certain groups in the medical field. For example, Congress requires that NIH "provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research" when "conducting and supporting programs for research, research training, recruitment, and other activities."[14] Likewise, NIH must make the Ruth L. Kirschstein National Research Service Award ("Kirschstein-NRSA")—the largest congressionally-mandated NIH training program—available in "a manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities), into fields of biomedical or behavioral research and in the provision of research training to women and such individuals."[15]

36. Third, Congress has required that NIH ensure "scientifically based strategic planning . . . through the development, implementation, and updating of [a] strategic plan," and that its resources "are sufficiently allocated for research projects identified in strategic plans."[16] Under this congressional mandate, NIH must develop its strategic plan no later than every six years and must submit that plan to Congress.[17] Congress also mandates specific strategic plans for each IC.[18] IC-specific strategic plans set forth research priorities within each institute, and by statute, each director must consider "the mission of the [IC] and . . . [its] strategic plan" "when review[ing] and mak[ing] the final decision with respect to making [a grant] award."[19]

37. Fourth, Congress mandates that, in creating its strategic plan for identifying its research priorities, NIH identify emerging scientific opportunities, flag near-, mid-, and long-term

[14] *Id.* at § 282(h) (emphasis added).
[15] 42 U.S.C. § 288(a)(4).
[16] 42 U.S.C. § 282 (b)(5), (6).
[17] *Id*. at (m)(1).
[18] 42 U.S.C. § 282(m)(3).
[19] 42 U.S.C. § 284(b)(3)(A)–(B).

scientific needs, assess opportunities for multi-institute research, and consider the "biological, social, and other determinants of health that contribute to health disparities."[20] These plans must be developed "in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders."[21]

38. Thus, Congress has long required NIH and ICs to set their priorities through science-based plans, and to study, understand, and address health equities and disparities in the field.

C. Types of NIH Grants

1. Project-Based Grants

39. Subject to the purposes and mandates articulated by Congress, NIH awards considerable funding for independent research through grants for scientific and biomedical research projects ("Project-Based Grants"), which usually are designated as part of the R-series of grants (*e.g.*, "R01," "R15," etc.). Though there are numerous categories of Project-Based Grants, the most typical designation for a Project-Based Grant is the R01, or "Research Project" grant. There are also certain grants that go to institutions that serve as coordinating centers that provide support, organize conferences, and assist researchers in applying for NIH funding in order to help advance studies in a particular field.

40. Project-Based Grants are the lifeblood of American biomedical and public health research. The billions of dollars each year in funding they provide contribute to medical and scientific breakthroughs that save lives and vitalize the economy. NIH touts, for example, that its

[20] 42 U.S.C. § 282(m)(2)(iii).
[21] *Id.* at (m)(4).

funding supports scientists working on projects to develop new technologies for medical imaging, to prevent the spread of HIV/AIDS, and to understand the rising rates of colorectal cancer.[22]

41. Such projects are critical to improving public health and have a demonstrable economic impact. For example, more than 30 percent of NIH-funded studies are later cited in an application for a commercial patent, demonstrating the vital role that Project-Based Grants play in fostering innovation.[23]

42. The funding provided by NIH's Project-Based Grants also provides financial support for researchers and institutions who have devoted themselves to the study of important public health issues. Funding from a Project-Based Grant may cover everything from the salary and benefits paid to principal investigators and more junior researchers to the cost of the facilities in which research is conducted. As a result, the abrupt termination of Project-Based Grants can have catastrophic consequences for the individuals who rely on grant funding to make a living and the institutions where their work occurs, not to mention the participants enrolled in any study made possible by that funding.

2. Pipeline Grants

43. In addition to Project-Based Grants, NIH also makes awards to institutions or individuals for career development or training ("Pipeline Grants"). Some Pipeline Grants are congressionally mandated, such as Kirschstein-NRSAs, which have the purpose of "training individuals" to conduct "biomedical and behavioral research . . . in matters relating to the cause,

[22] *NIH Science Highlights*, Nat'l Insts. of Health (Dec. 18, 2024), https://www.nih.gov/research-training/science-highlights.
[23] Elie Dolgin, *NIH research grants yield economic windfall*, 544 Nature 14 (2017).

diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health and Administration are directed."[24]

44. There are numerous kinds of Pipeline Grants. For example, training awards—"institutional training grants" (T32s)—are typically applied for by the senior investigator who heads a training or research center on behalf of a larger set of researchers at an institution, and they can be used to cover the costs of predoctoral or postdoctoral students. There are also individual grants, typically classified as F-series ("Fellowship") grants, or K-series ("Career Development") grants, that can be used to provide stipends to researchers at all stages of their career, cover tuition and costs, and fund other expenses.

45. Some Pipeline Grants are designed to promote recruitment of groups that are "underrepresented in the biomedical, clinical, behavioral and social sciences." For example, consistent with their congressional mandate, NIH protocols for Kirschstein-NRSA grants state that "[w]ithin the framework of the program's longstanding commitment to excellence and projected need for investigators in particular areas of research, attention must be given to recruiting prospective trainees from diverse backgrounds."[25]

46. Another Pipeline Grant—Maximizing Opportunities for Scientific and Academic Independent Careers ("MOSAIC") K99/R00—is designed to help promising postdoctoral researchers from diverse backgrounds transition into independent, tenure-track or equivalent

[24] 42 U.S.C. § 288(a)(1)(A).

[25] Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 11.3.3.3 (Apr. 2024). NIH identifies populations that are "underrepresented in the biomedical, clinical, behavioral and social sciences" to include racial and ethnic minorities, women, people with disabilities, and people from "disadvantaged backgrounds," determined by criteria such as current or prior homelessness, being in the foster care system, eligibility for free or reduced lunch or Pell grants, growing up in a rural area or low-income zip code, and having parents who did not complete higher education. *Id.* at § 11.3.3.4. All these categories are supported based on a reference to government data on educational or science workforce disparities. NIH's Grants Policy Statement further sets out the reasons for its policies to support the development of a diverse scientific workforce: "fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust." *Id.*

research-intensive faculty positions. Likewise, the "F31 Diversity" grant provides a five-year fellowship to individuals from backgrounds "currently underrepresented in the biomedical, clinical, behavioral, and social sciences."[26] Still another is the "Faculty Institutional Recruitment for Sustainable Transformation (FIRST) initiative," which aims to transform culture at NIH-funded institutions through the recruitment of faculty cohorts who have a demonstrated commitment to diversity and inclusion.[27]

47. Pipeline Grants are essential in shaping the careers of promising scientists, particularly those from disadvantaged backgrounds or from smaller institutions without significant private endowments. In 2022, more than 18,000 full-time graduate students received their primary federal funding support through NIH.[28] NIH funding programs provide essential support for promising undergraduate students at universities and colleges across the country.

48. These awards also have substantial impacts on the productivity and long-term retention of promising scientists in the field. In a 2011 study, researchers found that "receipt of an NIH postdoctoral fellowship leads to about one additional publication over the next five years, which reflects a 20 percent increase in research productivity.[29] A later National Bureau of Economic Review working paper found that researchers who have received fellowship awards were significantly more likely to subsequently complete an NIH-funded research project, further

[26] *See, e.g.,* Nat'l Insts. of Health, *Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)* (July 6, 2020), https://grants.nih.gov/grants/guide/pa-files/PA-20-251.html.
[27] *Supra* note 4, at 17.
[28] Nat'l Insts. of Health, *National Statistics: Primary Source of Federal Support for Full-Time Graduate Students* (Mar. 2024), https://report.nih.gov/nihdatabook/category/20.
[29] Brian A. Jacob & Lars Lefgren, *The Impact of NIH Postdoctoral Training Grants on Scientific Productivity*, 40 Res. Policy 864 (2011).

concluding that "NRSA postdoctoral fellowship awards have the potential to promote retention of scientists in NIH-funded research and in the biomedical workforce pipeline."[30]

D. The Grant Application Process

49. To offer funding for researchers outside of NIH, ICs post "Notices of Funding Opportunities" ("NOFOs"), alerting researchers to the availability of funds. While in some cases, grant-funded research is "investigator-initiated," meaning that the researcher comes to the funding IC with a proposed area of research, ICs "regularly identify specific research areas and program priorities to carry out their scientific missions."[31]

50. Funding awards are determined through a rigorous and competitive application process in which researchers submit their proposal and lengthy supporting documentation for review. Grant applications are substantial documents, often requiring months of effort and totaling 100 or more pages, including a detailed research plan, justifications of the proposed budget, information about facilities/locations, and letters of support from other researchers. Among other requirements, all applications must address how their research complies with NIH public policy requirements related to "inclusion of genders, members of minority groups, and individuals across the lifespan in clinical research."[32]

51. Upon completion of an application, the vast majority of grants—both Project-Based and Pipeline Grants—are subjected to a two-step, highly standardized peer-review process, as set forth in the Public Health Service Act, its enacting regulations, and detailed NIH protocols. Specifically, the NIH Director must "require appropriate technical and scientific peer review" of

[30] Misty L. Heggeness *et al., The Impact of Postdoctoral Fellowships on a Future Independent Career in Federally Funded Biomedical Research,* NBER Working Paper No. 24508 (Apr. 2018), https://www.nber.org/papers/w24508.
[31] Nat'l Insts. of Health, *New to NIH*, (2024), https://grants.nih.gov/new-to-nih.
[32] Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 2.3.6 (Apr. 2024).

"applications made for grants" for "biomedical and behavioral research."[33] NIH's stated policy is that "applications for funding submitted to NIH" will be "evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias."[34]

52. In the initial phase, the Center for Scientific Review receives applications, and then assigns applications to relevant scientific review groups, where groups of approximately twenty scientific reviewers who are experts in their field analyze and score each proposal.[35]

53. Scored applications are then moved on to IC-specific advisory councils, made up of "senior scientists with broad experience and members of the public with general knowledge of, and interest in, the IC's mission" where the IC determines which projects to move forward with funding.[36]

54. For Pipeline Grants, reviewers also "gauge the likelihood the fellowship will enhance [the applicant's] potential for and commitment to a productive research career. For postdoctorals, they also assess whether [the applicant] has what it takes to be an independent researcher."[37]

55. HHS regulations provide that "all" applications "shall be evaluated" and that the agency will either "1) approve, 2) defer because of either lack of funds or a need for further evaluation, or 3) disapprove support of the proposed project in whole or in part."[38] NIH policies

[33] 42 U.S.C. § 289a.
[34] Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 2.4 (Apr. 2024).
[35] *See* 42 C.F.R. § 52h (describing requirements for membership in scientific review groups).
[36] Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 2.4.3 (Apr. 2024).
[37] *See, e.g.*, Nat'l Inst. of Allergy & Infectious Diseases, Fellowship Grants (F) (Mar. 7, 2025), https://www.niaid.nih.gov/grants-contracts/fellowship-grants.
[38] 42 C.F.R. § 52.5.

effectuate these regulations.[39] NIH policy solely contemplates the agency withdrawing an application for consideration for "non-conformity with application requirements."[40]

56. There are no provisions in NIH guidelines that allow ICs to halt review of applications in specific grant lines because the agency has determined that a NOFO no longer effectuates agency priorities. Instead, NIH policy provides for the review of applications for "relevance to the IC's programs and priorities" at the IC advisory board stage of the process, which as discussed further below are set through the IC's strategic plan.[41]

57. After undergoing this rigorous, two-step peer review process, only a small percentage of all applications are selected to receive an award. Final authority to make an award belongs to the Director of the IC responsible for the grant.[42]

58. Upon selection, a successful applicant receives a Notice of Award ("NOA"). The NOA identifies the institutional grantee, one or more principal investigators, and specifies the amount of the award, its duration, and all other terms and conditions with which the grantee must comply.

59. The NOA also provides the grantee and principal investigators with contact information for their program officer, who is the main point of contact throughout the lifespan of the award. Generally, program officers are trained scientists well-versed in handling the subjects covered by the grants for which they are responsible.

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[39] *See, e.g.*, Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 11.3.4.1 (Apr. 2024) ("*Each* initial and competing continuation application *will be* evaluated for scientific merit by an NIH peer review group. Kirschstein-NRSA institutional research training grant applications also must be reviewed by the National Advisory Council or Board of the IC") (emphases added); *see also* Nat'l Insts. of Health, *First Level: Peer Review* (Sept. 9, 2024), https://grants.nih.gov/grants-process/review/first-level ("Each grant application submitted to NIH is evaluated according to established review criteria that must be stated clearly in a notice of funding opportunity").
[40] Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 2.3.9.5 (Apr. 2024).
[41] *Id.* at § 2.4.3.
[42] 42 U.S.C. § 284(b)(2).

60. Throughout the duration of the grant, grantees are required to provide annual progress reports to ensure compliance with grant terms. In response to these reports, program officers and grants management specialists conduct annual assessments to ensure that grantees are satisfying the grant's goals, terms, and conditions.

E. HHS Regulations Specify the Limited Grounds on Which Grant Terminations Must Be Based

61. The HHS regulations that are currently in effect significantly limit the termination of a grant, in whole or in part, during the duration of the award to specific circumstances: (1) if the grantee "fails to comply with the terms and conditions of the award"; (2) "for cause"; or (3) "with the consent of" the grantee.[43] Critically, NIH cannot terminate grants based on its determination that a grant "no longer effectuates the program goals or agency priorities." This is because the provision for terminating grants based on changes in goals or priorities appears in OMB guidance that HHS regulations did not adopt until a recent notice and comment rulemaking, and the *change to HHS regulations will not become effective until October of 2025*.

62. In 2013, OMB published the "Office of Management and Budget Guidance for Federal Financial Assistance, at 2 CFR part 200 ("OMB Uniform Guidance"). Though part of the CFR, this content, published in subtitle A, is "guidance, not regulation. Each Federal agency that awards grants has its own regulations in subtitle B. Federal agency regulations in subtitle B may

[43] 75 C.F.R. § 75.372. NIH written protocols are consistent with this regulatory limitation, providing for the process for termination solely on the request of a grantee or "if a recipient has failed to comply with the terms and conditions of award." Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 8.5.2 (Apr. 2024); *see also id.* at § 11.2.13.2, Termination Provision for Kirschstein-NRSA (solely provides for termination for individual awards upon awardee or trainee request or "if it determines that the recipient has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which it was made."); *id.* at § 11.3.16.2 (same, for institutional Kirschstein-NRSA); *id.* at § 12.13.3 (same for Research Career Development ("K") awards).

give regulatory effect to the OMB guidance, if the agency regulations require compliance with all or portions of the OMB guidance."[44]

63. The 2013 version of the OMB Uniform Guidance allowed for termination of a federal award solely under three limited conditions: (1) if the award recipient "fails to comply with the terms and conditions of a Federal award," (2) "for cause", or (3) "with the consent" of the grantee.[45]

64. HHS adopted this guidance in 2014 *as a regulation* and maintained the limitation that grants could be terminated only in those three narrow circumstances.[46] HHS subsequently revised its regulations in 2016 and retained the three limited conditions for termination in 45 C.F.R. § 75.372.[47]

65. In 2020, OMB made substantive amendments to the termination provision of the OMB Uniform Guidance.[48] The new termination provision—which is still only guidance without the effect of an agency regulation—continued to allow for termination for failure "to comply with the terms and conditions" of the award or upon the consent of the grantee.[49] However, OMB removed the third circumstance, which allows termination "for cause," and replaced it with language allowing for termination "to the greatest extent authorized by law, if an award no longer

[44] 2 C.F.R. § 1.105 (b)–(c) (2024).
[45] *See* 2 C.F.R. § 200.339 (2024) (OMB Uniform Guidance, 2013 version, available with subsequent 2020 redlines at infra note 48).
[46] *See Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*, 79 Fed. Reg. 75871 (Dec. 19, 2014) ("The Federal award may be terminated in whole or in part as follows:" if the award recipient "fails to comply with the terms and conditions of a Federal award," "for cause", or "with the consent" of the award recipient.)
[47] *See Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Technical Amendments*, 81 Fed. Reg. 3004 (Jan. 20, 2016).
[48] *See Office of Mgmt. & Budget, 2 CFR Revision Redline* 5 (Aug. 12, 2020), https://trumpadministration.archives.performance.gov/CAP/20200812-2-CFR-Revision-Redline_Final.pdf.
[49] 2 C.F.R. §§ 200.340(a)(1), (3).

effectuates the program goals or agency priorities."[50] OMB added a fourth condition, that the agency could terminate "pursuant to termination provisions included in the Federal award," and stated that the agency "should clearly and unambiguously specify termination provisions applicable to each Federal award, in applicable regulations or in the award, consistent with this section."[51]

66. HHS amended its regulations in November 2020, *but did not adopt the changes that OMB made in 2020 to its termination provision*. Instead, HHS regulations continued to allow termination only under the three limited circumstances of non-compliance, for cause, or with the consent of the awardee.[52]

67. In 2024, OMB again revised the termination provision in the OMB Uniform Guidance, effective October 1, 2025. Under the 2024 revision, agencies can terminate an award for non-compliance with the grant's terms and conditions, with the consent of the awardee, or "pursuant to the terms and conditions of the Federal award, including, to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities."[53] The OMB Uniform Guidance also states that the agency "must clearly and unambiguously specify all termination provisions in the terms and conditions of the Federal award."[54]

68. In October 2024, HHS published an interim final rule that will bring HHS regulations—*effective October 1, 2025*—into near total conformity with the OMB Uniform Guidance, including with 2 C.F.R. § 200.340. In the interim final rule, HHS stated that "HHS will forgo the separate codification, fully adopt 2 CFR part 200, reduce the total number of HHS-

[50] 2 C.F.R. § 200.340(a)(2) (2020).
[51] 2 C.F.R. §§ 200.340(a)(5), (b) (2020).
[52] *See* 45 C.F.R. § 75.373.
[53] 2 C.F.R. § 200.340(a) (1), (2), (4).
[54] 2 C.F.R. § 200.340(b).

specific changes, and codify those changes in 2 CFR part 300."[55] Therefore, beginning on October 1, 2025, *and not sooner*, HHS regulations will, for the first time, allow agencies to terminate grants "pursuant to the terms and conditions of the Federal award, including, to the extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

69. Notwithstanding the termination letters and revised NOAs described below that NIH has sent to Plaintiffs and their members citing that the grants "no longer effectuate[] agency priorities" as the authority to terminate their grants, NIH does not have such authority under current HHS regulations. Nor is there anything in the terms and conditions of the NOAs that Plaintiffs initially received when the awards were made that provide or can provide NIH with such authority. Plaintiffs' original NOA lists various terms and conditions and explicitly incorporate 45 C.F.R. Part 75. The NOAs do not list 2 C.F.R. Part 200 explicitly as an applicable term or condition.

70. The NOAs also state that they incorporate the Grants Policy Statement, which is not a formal regulation, but is instead "an aid to the interpretation of statutory and regulatory requirements."[56] In the revised NOAs that NIH sent to Plaintiffs when it terminated their grants, NIH stated that "NIH is taking this enforcement action in accordance with 2 CFR § 200.340 as implemented in NIH [Grants Policy Statement] Section 8.5.2." But this is an inaccurate statement of applicable regulations. Section 8.5.2 of the Grants Policy Statement did *not* implement the revised 2020 version of 2 C.F.R. 200.340 because HHS did not implement that revised version in its regulations. NIH Grants Policy Statement states: "These terms and conditions are intended to be compliant with governing statutes and the requirements of 2 CFR Part 200, *as modified by previously approved waivers and deviations*. However, in the case of a conflict, the statutes and

[55] *Health and Human Services Adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*, 89 Fed. Reg. 80,055, 80,056 (Oct. 2, 2024).
[56] Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 3 (Apr. 2024) (emphasis added).

regulations govern."[57] Because HHS's adoption of 2 C.F.R. § 200.340 is not yet in effect, HHS's current termination regulation remains a "deviation" from 2 C.F.R. § 200.340 and HHS's limited grounds for termination still apply.

71. Terminations at NIH are historically rare. In response to noncompliance, "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. However, NIH may decide to terminate the grant if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate a grant when necessary, such as to protect the public health and welfare from the effects of a serious deficiency."[58]

72. As one NIH official stated, "Terminations are the *final* option." Indeed, reporting indicates that, prior to January 2025, NIH terminated around 20 grants a year on average, "and usually only because of serious problems, such as flagrant misconduct, fraud, or an ethical breach that could harm study participants." The standard approach at NIH has long been to not terminate existing grants even if they address a low programmatic or agency priority. As a former NIH official who worked at the agency for several years described, "I have been involved with legitimate grant terminations," and, "I can count them on the fingers of one hand."[59]

F. NIH's Strategic Plan Guides the Review of Grants

73. The NIH-Wide Strategic Plan outlines NIH's vision for biomedical research direction, capacity, and stewardship by articulating the highest priorities of NIH for a 5-year

[57] Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 3 (Apr. 2024).
[58] Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 8.5.2 (Apr. 2024).
[59] Katherine J. Wu, *The NIH's Grant Terminations Are 'Utter and Complete Chaos,'* THE ATLANTIC (Mar. 14, 2025), https://www.theatlantic.com/health/archive/2025/03/nih-grant-terminations/682039/.

period. The plan is designed to complement and harmonize IC strategic plans across NIH, which address their individual missions.[60]

74. The current NIH-Wide Strategic Plan governs from July 2021 until September 30, 2025, but creation of the plan began well before then, in September 2019. The four-phase strategic planning process involved: (1) pre-planning, (2) gathering internal input and development of the Strategic Plan framework, (3) gathering input from external stakeholders, and (4) drafting and publishing the Strategic Plan.[61]

75. The NIH Strategic Plan sets forth three objectives: (1) advancing biomedical and behavioral sciences; (2) developing, maintaining, and renewing scientific research capacity; and (3) exemplifying and promoting the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science—across which NIH has identified several "crosscutting themes," which include "improving minority health and reducing health disparities."[62]

76. In line with the congressional mandate to consider health disparities, the NIH Strategic Plan "prioritizes research that addresses the needs of underserved populations to address the factors that contribute to health disparities" including by "identifying key gaps in prevention science related to health disparities and promoting targeted research on appropriately tailored public health, clinical, and community preventive services in diverse settings and contexts."[63]

77. Similarly, the NIH Strategic Plan describes research to effectuate Congress's mandate to consider the "disease burden in the United States."[64] Suicide, for example, is

[60] *NIH-Wide Strategic Plan*, *supra* note 4.
[61] *Id.*
[62] *Id.* at 3.
[63] *Id.* at 11.
[64] 42 U.S.C. § 282 (2)(b)(iii).

disproportionately prevalent in specific populations, including sexual and gender minority populations, and NIH research into suicide prevention illustrates how improvements in care can save lives.[65]

78. The NIH Strategic Plan also recognizes that the "strength of the NIH workforce depends on its sustainability and diversity."[66] Through the congressionally required "Next Generation Researchers Initiative," NIH aims to achieve sustainability by "enhanc[ing] opportunities for early-stage researchers by prioritizing funding of independent research applications" of early-stage researchers "such as policies to . . . enhance workforce diversity."[67]

79. ICs also go through a strategic planning process and have plans currently in place. For example, the National Institute for Minority Health and Health Disparities' strategic plan summarizes evidence demonstrating health disparities faced by people from minority racial and ethnic backgrounds, sexual and gender minorities, rural residents, and individuals of less privileged socioeconomic status including shorter life expectancy; higher rates of cardiovascular disease, cancer, diabetes, infant mortality, stroke, cognitive impairment, asthma, sexually transmitted infections, and dental diseases; and differences in prevalence and outcomes of mental illness. That plan also sets forth "a commitment by NIH to support research aimed at addressing risk and protective factors that operate and interact on multiple levels to impact the well-being of health disparity populations."[68]

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[65] *NIH-Wide Strategic Plan*, *supra* note 4, at 9.
[66] *Id.* at 16.
[67] 42 U.S.C. § 283o; *id.*
[68] Nat'l Insts. of Health, *Minority Health and Health Disparities Strategic Plan 2021–2025* (2021), https://nimhd.nih.gov/docs/strategic-plan/NIH-Wide_MHHD_Strategic_Plan_2021-2025_508.pdf at 4, 8. The current version of the plan available on NIH's website states that it "is being implemented through December 31, 2025," https://nimhd.nih.gov/about/strategic-plan/.

G. President Trump Issues Executive Orders that Ignite Chaos at NIH

80. Starting on January 20, 2025, President Donald. J. Trump issued a series of executive orders broadly seeking to end all efforts related to "equity"—including specifically with respect to any federal grants. Even after being enjoined, these executive orders nonetheless prompted Defendants to issue the unlawful Directives at NIH.

81. Executive Order No. 14151, dated January 20, 2025 and entitled "Ending Radical and Wasteful Government DEI Programs and Preferencing," instructs the Attorney General and others to "coordinate the termination of all discriminatory programs, including illegal DEI and 'diversity, equity, inclusion, and accessibility' (DEIA) mandates, policies, programs, preferences, and activities in the Federal Government, under whatever name they appear." Additionally, it directs each federal agency head to "terminate, to the maximum extent allowed by law, all… 'equity-related' grants or contracts" within 60 days.[69]

82. The next day, on January 21, 2025, President Trump issued Executive Order No. 14173, entitled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity." To address the purported "immoral race- and sex-based preferences under the guise of so-called [DEI] or [DEIA]," the order requires the Director of OMB to "[e]xcise references to DEI and DEIA principles, under whatever name they may appear, from Federal acquisition, contracting, grants, and financial assistance procedures" and to "[t]erminate all 'diversity,' 'equity,' 'equitable decision-making,' 'equitable deployment of financial and technical assistance,' 'advancing equity,' and like mandates, requirements, programs, or activities, as appropriate."[70] Provisions of

[69] *Ending Radical and Wasteful Government DEI Programs and Preferencing*, 90 Fed. Reg. 8339 (Jan. 20, 2025).
[70] *Ending Illegal Discrimination and Restoring Merit-Based Opportunity*, 90 Fed. Reg. 8633, 8634 (Jan. 21, 2025).

this executive order and Executive Order No. 14151 were enjoined between February 21 and March 14, 2025.[71]

83. On January 20, 2025, President Trump also issued Executive Order 14168, "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," directing that "federal funds shall not be used to promote gender ideology," instructing federal agencies to revise grant conditions accordingly, and defining "gender ideology" as a "false claim" that "replaces the biological category of sex with an ever-shifting concept of self-assessed gender identity," and that "includes the idea that there is a vast spectrum of genders that are disconnected from one's sex."[72] Provisions of this executive order were enjoined on February 28, 2025.[73]

84. On January 27, 2025, OMB issued a memorandum directing all federal agencies—including NIH—to "temporarily pause all activities related to obligation or disbursement of all Federal financial assistance, and all other relevant agency activities that may be implicated by," among others, "[Executive Orders above], including, but not limited to, financial assistance for… DEI, woke gender ideology, and the green new deal." Provisions of this memorandum were enjoined on January 31, 2025.[74]

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[71] *See Nat'l Assn. of Diversity Officers in Higher Education v. Trump*, No. 25-cv-0333-ABA (D. Md. Feb. 21, 2025) ECF No. 45 (preliminarily enjoining provisions requiring agencies to terminate equity-related grants); *Nat'l Ass'n of Diversity Officers in Higher Educ. v. Trump*, No. 25-1189 (4th Cir. Mar. 14, 2025), ECF No. 29 (staying preliminary injunction pending appeal).

[72] *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8615 (Jan. 20, 2025).

[73] *Washington v. Trump*, No. 2:25-cv-244-LK (W.D. Wash. Feb. 28, 2025) ECF No. 50 (on February 28, 2025, preliminary enjoining sections that condition, withhold, or end federal funding in Plaintiffs states Colorado, Minnesota, Oregon, and Washington); *PFLAG, Inc. v. Donald J. Trump*, No. 8:25-cv-00337-BAH (D. Md. Mar. 4, 2025) ECF No. 116 (on March 4, 2025, preliminarily enjoining the same nationwide).

[74] *New York v. Trump*, No. 25-cv-39-JJM-PAS (D.R.I Jan. 31, 2025), ECF No. 50 (preliminarily enjoining federal agency defendants from "pausing, freezing, blocking, canceling, suspending, terminating, or otherwise impeding the disbursement of appropriated federal funds to the States under awarded grants, executed contracts, or other executed financial obligations," based on both the OMB directive and Executive Orders, including the DEI and Gender Ideology executive orders).

H. NIH Issues Directives to Purge Research Grants

85. Historically, the longstanding firewall between an administration's *political* choices and NIH's *scientific* peer review process ensured the agency avoided the massive waste and disruption to researcher careers, participant well-being, and public health that would accompany mid-stream research terminations. But since January 20, 2025, NIH has veered sharply from this deliberative, reasoned, and methodical approach.

86. The Executive Orders, although enjoined in part, have prompted a massive purge in NIH grants and funding streams untethered to congressional mandates, the operative NIH Strategic Plan, or any reasoned review process. As explained below, in response to the Executive Orders, NIH has issued a series of documents vaguely articulating areas of research that purportedly "no longer effectuate[] agency priorities." These documents—titled as "guidance" but including mandatory language and referred to herein as the Directives—include memoranda developed by HHS and NIH (issued on or around February 28, 2025 and on March 25, 2025) and other versions of these documents that convey the same mandate.

87. This process began on February 12, 2025, when NIH issued a memorandum stating that it "is in the process of reevaluating the agency's priorities based on the goals of the new administration."[75] That memorandum goes on to say that "NIH will effectuate the administration's goals over time, but given recent court orders, this cannot be a factor in IC funding decisions at this time." The memorandum also indicates that, "[a]dditional details on future funding actions related to the agency's goals will be provided under a separate memo."

88. NIH would provide those additional details over the next few weeks—including the very next day, when NIH issued another memorandum to IC chief grant management officers

[75] Judd Legum, *Breaking: NIH Admits Funding Freeze is Illegal,* POPULAR INFORMATION (Feb. 12, 2025), https://popular.info/p/breaking-nih-admits-funding-freeze.

("February 13 Memo"). That memo announced "hard funding restrictions" on "awards where the program promotes or takes part in diversity, equity, and includsion [sic] ('DEI') initiatives" with those restrictions applying "to new and continuation awards made on or after February 14, 2025."[76] The memorandum also states, "[i]f the sole purpose of the grant, cooperative agreement, other transaction award (including modifications), or supplement supports DEI activities, then the award must be fully restricted. The restrictions will remain in place until the agency conducts an internal review for payment integrity."

89. Soon after, NIH took steps to inventory projects for its purge of disfavored grants—including the termination of Project-Based Grants and Pipeline Grants at issue here—across various ICs. As one NIH official described the agency's actions throughout this spree, "[i]t is such utter and complete chaos."[77] "In advance of the terminations… agency leadership solicited grants that might, for instance, 'promote gender ideology,' or that involved certain types of vaccine-behavior research."[78] NIH officials responded with lists of grants to terminate. One official described the lists as looking like "someone had performed a Ctrl+F search for certain terms, then copied and pasted the results" and directed the cancellation of those grants.[79]

90. Directions to terminate grants came without warning to the typical NIH officials who would be involved in the process, without the usual level of rigor and deliberation that accompanies a potential termination, and without any allegations or findings of noncompliance by grantees. The directions "instructed grants-management officers to issue letters by the end of the

[76] Stephanie Mencimer, *NIH Is Defying a Federal Court and Freezing Research Funding Anyway*, MOTHER JONES (Feb. 24, 2025), https://www.motherjones.com/politics/2025/02/nih-defying-federal-court-freeze-research-funding-dei-temporary-restraining-order/; screenshot of February 13 Memo, MOTHER JONES (Feb. 24, 2025), https://substackcdn.com/image/fetch/f_auto,q_auto:good,fl_progressive:steep/https%3A%2F%2Fsubstack-post-media.s3.amazonaws.com%2Fpublic%2Fimages%2F7e116a29-f20d-435d-a8ba-ba18cea529d8_1182x1236.png.
[77] Wu, *supra* note 59.
[78] *Id.*
[79] *Id.*

day they received them . . . leaving no time to push back, or even react," eliminating any meaningful role the grants-management officers could have played in these decisions.[80] "In at least one case, . . . a program officer learned that their grantee's award had been terminated from the grantee," *not from the NIH*.[81]

91. Throughout February and March 2025, NIH issued Directives for assessing grant awards that expanded the scope of the purge.

92. On or around February 28, 2025, NIH issued staff "guidance" ("February 28 Guidance") that rescinded the February 13 Memo but expanded on its core anti-DEI messaging, stating: "NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI) . . . Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims[,] assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities."[82] The memorandum also instructs officials to "completely excise all DEI activities[.]"

93. The February 28 Guidance identifies four categories of awards and mandates actions for each category deemed "DEI related":

- "Category 1" — the "sole purpose of the project is DEI related (e.g., diversity supplements or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that was unpublished as outlined above." For projects construed as Category 1, "ICs must not issue the award."

- "Category 2" — the project "partially supports DEI activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope) this [sic] means DEI activities are

[80] *Id.*
[81] *Id.*
[82] *See* Max Kozlov and Smriti Mallapaty, *Exclusive: NIH to terminate hundreds of active research grants*, NATURE (Mar. 6, 2025), https://www.nature.com/articles/d41586-025-00703-1; *see also* Carolyn Y. Johnson and Joel Achenbach, *NIH reels with fear, uncertainty about future of scientific research*, THE WASHINGTON POST (Mar. 5, 2025), https://www.washingtonpost.com/science/2025/03/05/nih-trump-turmoil-grants/.

ancillary to the purpose of the project [sic]. In some cases, not readily visible [sic]." For projects construed as Category 2, "[i]f the IC and the applicant/recipient cannot reach an agreement" to renegotiate the scope of the project, "or the project is no longer viable without the DEI related activities, the IC cannot proceed with the award." For any such ongoing project, "the IC must work…to negotiate a bilateral termination of the project," but "[w]here bilateral termination cannot be reached, the IC must unilaterally terminate the project."

- "Category 3" — the project "does not support DEI activities, but may contain language related to DEI (e.g., statement regarding institutional commitment to diversity in the 'Facilities and Other Resources' attachment and terminology related to structural racism—this is not all-inclusive)." For projects construed as Category 3, ICs "must request an updated [application or progress report] with the DEI language removed," and only once the language has been removed may the IC "proceed with issuing the award."

- "Category 4" — the project does "not support any DEI activities." ICs "may proceed with issuing the award."

94. The February 28 Guidance also provides "[g]uidance for staff to use when terminating awards identified by HHS or the IC." In those circumstances, NIH officials must "issue a revise[d] NOA." The February 28 Guidance also instructs NIH officials to "[u]se the following termination term" in the revised NOA: "This award related to *[select the appropriate example relevant to your project by choosing one of the highlighted examples DEI, China, or Transgender issues* (sic)*]* no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award is terminated [Refer to Appendix 3 for language provided to NIH by HHS.]" (emphasis added). The document also instructs NIH officials that "[t]ermination actions taken based on agency priorities do not require appeals language because the action was *not* based on administrative nor [sic] programmatic noncompliance" (emphasis added). In addition, the February 28 Guidance directs, "[i]f the grant is a no cost extension, and the HHS requests a termination, the project must be terminated."

95. Appendix 3, in turn, lists "[l]anguage provided to NIH by HHS" with "examples for research activities that NIH no longer supports," and outlines three forbidden topics:

- "China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives."

- "DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ('DEI') studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harm the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."

- "Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs."

96. On March 25, 2025, as part of its Directives, NIH issued another document (the "March 25 Guidance") with a header that warned, "INTERNAL: NOT FOR DISTRIBUTION OUTSIDE THE GOVERNMENT."[83]

97. Like the February 28 Guidance, the March 25 Guidance outlines categories of projects and mandating action for certain forbidden categories:

- Category 1 projects remain the same, and the March 25 Guidance likewise requires that NIH officials terminate all such existing projects and not issue any such awards.

- Category 2 projects are those that "partially support[] non-NIH/HHS priority/authority activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope). This means the non-NIH/HHS priority/authority activities are ancillary to the purpose of the project, in some cases, not readily visible [sic]." The document also notes that, "Activities required to comply with NIH inclusion policies are not considered DEI activities."

[83]Max Kozlov, *Exclusive: NIH to cut grants for COVID research, documents reveal*, NATURE (Mar. 26, 2025), https://www.nature.com/articles/d41586-025-00954-y.

- Category 3 projects have a different definition and "do[] not support any DEI activities." The memo states that the "IC may proceed with issuing the award."

- Category 4 projects have a different definition and are designated "HHS Department Authority Terminations." The "Director, NIH or designee" provides a list of these projects to NIH officials, and the officials must in turn "issue termination letters" for these projects.

- Category 5 projects are those awarded "to [e]ntities in certain foreign countries." According to that part of the document, "Additional guidance on awards to foreign entities is forthcoming. At this time, ICs should hold all awards to entities located" in certain countries, including South Africa.

98. This document repeats much of the substance of the February 28 Guidance, including that "NIH will no longer prioritize research and research training programs that focus on [DEI]," but expands the topics of research NIH purports to "no longer prioritize" to include "Vaccine Hesitancy" and "COVID-related" research. It directs NIH officials to include the following language (or language substantially similar) in correspondence regarding grant reviews: "It is the policy of NIH not to prioritize [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa, etc.]."

99. The March 25 Guidance also identifies—in a section labeled "Appendix 3"—a list of forbidden topics for NIH grants and prescribes language to be included in termination letters. This document is identical to the March 25 Guidance with respect to identifying "China," "DEI," and "Transgender issues" as areas of forbidden research, but it also provides required language to terminate projects in the two additional forbidden topics—"Vaccine Hesitancy" and "COVID-related" research:

- "Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses [sic] gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in

ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria."

- "COVID: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary."

100. Like the February 25 Guidance, the March 25 Guidance directs NIH officials to revise NOAs that are terminated pursuant to the Directives, and instructs NIH officials to include the following (or substantially similar) language in those revisions: "It is the policy of NIH not to prioritize [insert termination category language from Appendix 3, verbatim]. Therefore, this project is terminated."

101. The March 25 Guidance also has an FAQ section that includes, among other instructions: "6. When ICs issue revised NOAs to terminate awards, do they have to use the exact language provided by HHS in the termination term? Yes, ICs must use the exact language provided in Appendix 3, with no edits."

102. In addition, regarding "Notice of Funding Opportunity (NOFO) Guidance," the document has only the following text: "[pending]."

103. The Directives—comprised of the February 28 Guidance, the March 25 Guidance, and other versions of these documents that articulated areas of research that purportedly "no longer effectuate[] agency priorities"—fail to define critical terms, such as "diversity, equity, and inclusion" or "DEI"; "artificial and non-scientific categories"; "amorphous equity objectives"; "[t]ransgender issues"; "gender identity"; or "COVID-related."

104. The lack of clarity about the meaning of these and other forbidden terms has contributed to widespread confusion among NIH staff on how to implement the mandates outlined

in the Directives.[84] For example, as one NIH official asked, "is a grant providing culturally appropriate care specifically to Hispanic and Latino population 'discrimination'?"[85]

I. Pursuant to Directives, NIH Issues Boilerplate Notices to Terminate Hundreds of Grants

105. Pursuant to the Directives, NIH adopted a script for grant termination notices. It did so without regard for the limited circumstances in which terminations may be made and its legal obligation to individually and rigorously review the varied and diverse projects under consideration for termination.

106. Each termination notice begins by identifying the project number, identifying which year's Grants Policy Statement applies to the grantee's project, and stating that the letter "constitutes a notice of termination" purportedly pursuant to that Grants Policy Statement and 2 C.F.R. § 200.340(a)(2). The notice also emphasizes that "obligations generally should be determined by reference to the law in effect when the grants were made."

107. Citing the pertinent year's Grants Policy Statement, each notice states, "At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination '[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.'"

108. From there, each notice includes one of a few slightly different scripts stating, without explanation, that the grant "no longer effectuates agency priorities." The language in these notices repeats the mandatory language from the appendices, described above. Below are three examples:

- First, "This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of

[84] *See* Wu, *supra* at note 59.
[85] Kozlov et al. *supra* at note 82.

> NIH not to prioritize these research programs. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria." ("Termination Section 1"). In some notices, "DEI" is substituted for "gender identity."
>
> - The second script is the same as the first but omits the last two sentences ("Termination Section 2").
>
> - The third script provides, "This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ('DEI') studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs." ("Termination Section 3").

109. After that, the language across all notices is once again nearly identical, stating the following or something substantially similar, "Although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision, no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities."

110. After this emphasis on the futility of any appeal, each notice outlines the appeals process. But as one NIH staffer stated, "the language included in the terms of the terminated grants about the appeal process is CYA [to cover their asses] and any appeal will end up in the trash."[86]

111. For the vast majority, if not all, terminated grants since February 28, 2025—including all terminated Project-Based Grants and Pipeline Grants supporting the research of

[86] Max Kozlov, Bluesky (Mar. 31, 2025, 2:24 PM), https://bsky.app/profile/maxkozlov.bsky.social/post/3llp6vhkvx22t.

Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members—the notices offer no other justifications for termination.

112. The notices make no effort to explain how or why the relevant grant fails to "effectuate agency priorities" or otherwise warrant termination. The notices fail to cite any project-specific information or data, much less any reasons to disregard that information or data. Indeed, the assertions in the termination notices about the lack of scientific validity, rigor, or public health benefit of the studies contradict the conclusions of NIH and external scientists who previously reviewed these projects and helped award those grants in the first place, including the multiple panels of experts in the grantees' fields who judged the proposals on criteria such as the lead scientist's track record, the rigor of the study's design, and the project's likelihood of addressing a pressing biomedical-research issue.[87] These notices also do not address NIH's prior assessment that the projects *do* meet agency priorities and are aligned with the statutory mandate and goals of NIH and the pertinent IC.

113. The notices also demonstrate that NIH failed to consider any reliance interests at stake for ongoing grants. For example, the notices say nothing about potential job losses that would result from the termination of the grant at issue or the effect the termination would have on study participants, the data being collected, the populations served by the research, or the broader goals furthered by the study. In short, the notices say nothing about how these terminations may affect the research endeavor or public health. Indeed, as one member of senior leadership at an NIH institute stated, grants are getting killed "without any scientific input anywhere."

114. For grants that were terminated, NIH also issued revised NOAs with new end-of-project dates that reflected immediate or near-immediate termination. These revised NOAs also

[87] *See* Wu, *supra* at note 59.

included new termination language with statements that were substantively similar to the language included in Appendix 3 of the February 28 Guidance and March 25 Guidance, and made explicit reference to "2 C.F.R. §200.340 as implemented in NIH [Grants Policy Statement] Section 8.5.2" as its statutory authority for these terminations.

115. Evidence suggests the language in the termination notices did not originate with NIH or HHS staff but was instead drafted by staff from the Department of Government Efficiency ("DOGE"). For example, metadata associated with at least one such notice shows it was authored by "JoshuaAHanley." An attorney named Joshua A. Hanley, a 2021 law school graduate, works at DOGE.[88]

116. The terminations cut across diverse topics *that NIH is statutorily required to research*. At least 678 research projects have been terminated to date. These include projects on some of the most pressing public health issues of our time, including breast cancer, uterine cancer, anal cancer, stroke risk, cardiac health, Alzheimer's Disease, HIV prevention, suicide prevention, alcohol use disorder, smoking cessation, eating disorders, sexually transmitted infections, COVID-19, depression, psychopathology, pain, and many other conditions that disproportionately burden minority communities. Other terminated grants studied the harmful effects of discrimination, poverty, racism, loneliness, trans exclusionary policies, and social stress, as well as the health-protective effects of social support, education, and school-based mental health interventions. Still others have no clear or at most a tangential connection to DEI, gender identity, or the other now-disfavored topics that were the alleged basis for their termination. These terminations compromise

[88] Sara Reardon, *Trump officials will screen NIH funding opportunities*, SCIENCE (Mar. 26, 2025), https://www.science.org/content/article/trump-officials-will-screen-nih-funding-opportunities. More recently, media reported that after a two-month freeze on posting NOFOs, NIH will resume posting NOFOs, but only after review by HHS and DOGE for consistency with administration priorities.

NIH's ability to fulfill its statutory and other obligations. They also compromise the public's health and deprive minority communities of equal access to the benefits of government research.

117. The terminations also directly conflict with NIH strategic priorities. For example, the 2021–25 Strategic Plan for the National Institute on Minority Health and Health Disparities prioritizes research, among other things, to "understand and to improve the health of racial/ethnic minority populations," to "[a]dvance scientific understanding of the causes of health disparities," and to "[d]evelop and test interventions to reduce health disparities."[89] Consistent with this goal, that institute issued Grant Number 5R01MD017509 for a five-year intervention beginning May 14, 2022, to test whether directly reducing the income gap among older African American men in rural communities enhances their health and wellbeing. The grant was scheduled to last through January 2027. However, on March 14, 2025, half-way through the project, the grant was terminated. In another instance, the institute funded a proposed multi-year grant entitled, "Development of a School-Based Prevention Intervention to Promote Adolescent Mental Health Equity." The grant began on January 31, 2025, but was terminated without explanation just 40 days later. These grants exemplify a pattern, in which IC-specific directors awarded grants consistent with their IC-specific strategic plans, after which the grants were summarily terminated despite no change to IC-specific or overall NIH strategic plans.

118. The programs designed by NIH to implement Congress's statutory mandate to diversify the workforce are also being gutted. In the past four weeks, NIH has at least terminated seventeen F31 Diversity awards that support promising graduate students in their final years of dissertation research.

[89] *Nat'l Insts. of Health*, *supra* note 68 at 2.

119. Similarly, NIH has paused all work under the Undergraduate Research Training Initiative for Student Enhancement ("U-RISE"), a $23.1 million NIH initiative launched in 2019, "to develop a diverse pool of undergraduates" who plan to pursue higher education and careers in biomedical research.[90] U-RISE is a mirror program to the Minority Access to Research Careers program ("MARC"), created in 1977.[91] Universities develop, apply for, receive, and administer MARC and U-RISE grants. For nearly 50 years, these programs have operated to diversify the biomedical workforce, supporting thousands of students from underrepresented backgrounds.

120. In 2024, NIH supported 63 U-RISE and 34 MARC programs. On March 27, 2025, with no prior notice, NIH issued stop work orders for all U-RISE programs through an email stating that "NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities." The email instructs the program directors to "cease project activities as of the current budget period end date of 3/31/25" with an additional four days to reconcile all expenditures. It appears that all U-RISE program directors have received the same communication, regardless of how many years were left on these five-year awards. MARC program officers have no idea if or when their identical programs will be paused or terminated.

121. U-RISE supports high-achieving undergraduate students, typically juniors and seniors, who have demonstrated academic promise in STEM disciplines. The program aims to increase the likelihood that these students will pursue and complete PhDs in biomedical research fields by providing tuition assistance, monthly stipends, research training, mentoring, and support

[90] Nat'l Insts. of Health, *Undergraduate Research Training Initiative for Student Enhancement* (expired) https://grants.nih.gov/grants/guide/pa-files/par-19-218.html.

[91] Nat'l Ctr. for Biotechnology Information, *Meeting the Nation's Needs for Biomedical and Behavioral Scientists, Appendix A, Historical Overview*, (1994), https://www.ncbi.nlm.nih.gov/books/NBK236727/. The program's name has since changed to "Maximizing Access to Research Careers," but its core goal has remained the same for 48 years, i.e., "to create and sustain inclusive [undergraduate] training environments for trainees from diverse backgrounds."

for lab-related expenses. The sudden termination of funding places participating students at immediate risk of losing housing, income, and academic continuity.

122. Along with terminations, NIH is also violating its regulatory mandate to review all appropriately submitted applications.

123. In February 2025, the F31 Diversity track opportunity disappeared from NIH websites.[92] While in the past NIH has maintained expired funding opportunities on its website with an indication that the opportunity has expired, links to the F31 Diversity track now result in a "page not found" message. NIH has not provided information on the fate of applications received for these unpublished opportunities, but the March Guidance indicates that applications "received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority" will not be funded.

124. These losses will render NIH incapable of meeting its congressionally required responsibilities. And they will deeply compromise the next generation of scientists, denying the public the contributions to health their promising careers would have yielded.

J. Terminations of Plaintiffs' Grants Cause Confusion, Chaos, and Other Ongoing Harm

125. The termination of the research funding of Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members provides a window into the devastation to medical and scientific research playing out across the nation right now. Their stories—just a fraction of the chaos and harm caused by the Directives—show how large the blast radius is from these terminations. And although the subject matter of their research spans all types of subject matter and populations, each termination notice is identical except for ever-so slightly different scripts stating that the grant "no

[92] F31 Diversity grants are far from the only programs impacted. Additional unpublished funding opportunities include the MOSAIC, U-RISE, MARC and dozens of others.

longer effectuates agency priorities" (*see* above descriptions of Termination 1, Termination 2, and Termination 3).

126. As detailed further below, across Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members, these terminations have resulted in studies being postponed or cancelled, putting at risk the health of participants. And the terminations have severely diminished—if not eviscerated—the reliability of any data or statistical analyses from those years-long research efforts, crippling scientific advancement for years to come. Whether weighing the effects on study participants or the broader field of study, the lost benefits to the populations served by their research, or even the financial consequences on themselves and their staff, each researcher has suffered severe distress because of the Directives. Science may be a collective endeavor, but the harms here have also struck Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members on a personal level.

127. What's more, based on the Directives and the conclusory nature of the termination letters, Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members do not know which of their current remaining projects—if any—are still eligible for NIH grants, and they fear that at least some of their ongoing NIH-funded projects are at risk of being terminated on similar grounds. Individual Plaintiffs, Plaintiff Ibis, and Associational Plaintiffs' members are also uncertain about how they may need to change their current and future research, what terminology they must avoid, as well as which populations their research can focus on to remain eligible for NIH funding. As such, although they intend to apply for future NIH grants, they have no idea how to propose research in their areas of expertise that would satisfy the "agency priorities."

1. Individual Plaintiffs

128. Plaintiff Charlton has received terminations for her entire portfolio of five NIH grants, including a five-year $4.15 million R61 grant for an observational study of the mental health impact of legislative bills targeting the LGBTQ population; a five-year $4.42 million R01 grant for a longitudinal study of worse obstetrical outcomes for LGBQ women as compared to heterosexual women to inform targeted interventions to improve their health and the health of the approximately 800,000 children born each year to this population (a project that has nothing to do with gender identity and includes no transgender study participants); and an administrative supplement of $100,000 for the R01 grant to support an early-career trainee on the research team. These grants were terminated throughout March with notices that used Termination Section 2 (Gender Identity), Termination Section 3 (DEI), and Termination Section 2 (Gender Identity), respectively.

129. Because of these terminations, Dr. Charlton has lost nearly all of her salary as well as the money to pay the salaries of 18 people on her staff. She had to terminate the LGBTQ Health Center's director the day after the terminations. And she has had to suddenly cancel appointments with impacted youth and other research subjects and wind down her projects.

130. NIH has terminated at least six grants in support of Plaintiff Edwards' research. The total amount awarded across those grants is approximately $11.9 million. Included in those terminations is a five-year $3.8 million R01 grant for a longitudinal study among sexual minority men to identify factors predicting sexual assault experiences and outcomes to inform prevention and intervention efforts specific to this highly vulnerable group. Also among those cuts is a R34 research grant, titled *An Online Family-based Program to Prevent Alcohol Use and Dating and Sexual Violence among Sexual and Gender Minority Youth*, aiming to increase family support and

communication, enhance social-emotional skills, and increase awareness of accurate perceptions of alcohol and dating violence norms. Both programs were terminated in March 2025 with notices that used Termination Section 1 and 2 (Gender Identity), respectively.

131. Due to the grant terminations, Dr. Edwards has had to suddenly stop or severely curtail research projects funded through the grants, potentially halting the intervention for the 22 families that are enrolled in one of her programs and impairing her ability to analyze data and build preventative interventions through the data collected in the projects. Further, one goal of her R34 research grant is to identify ways to implement programmatic recommendations for families in places like churches, community centers, and schools; now due to the termination, she will not have the data to evaluate or propose these types of recommendations from the project. Dr. Edwards has also lost a portion of her salary because of these terminations, as well as the ability to continue to pay a number of the approximately 50 staff members who are funded through her research grants.

132. Plaintiff Lurie served as a paid consultant and advisor on a two-year $277,552 R21 grant to evaluate the impacts of over-the counter access to pre-exposure prophylaxis ("PrEP") on reduce the risk of HIV transmission. On March 21, 2025, the grantee institution, Harvard Pilgrim Healthcare, Inc., received a termination notice from NIH using Termination Section 2 (Gender Identity).

133. As a result of the termination, the research into PrEP access being conducted under the grant has been discontinued, resulting in harms to public health in the form of reduced knowledge about how to effectively reduce the spread of HIV.

2. Plaintiff APHA Members

134. Members of Plaintiff APHA have also received letters notifying them that NIH grants supporting their research had been terminated.

135. For example, APHA Member 1 was awarded a five-year, $4 million grant in support of their research to study time-efficient ways to measure patients' exposure to discrimination based on race, sex, gender identity, sexual orientation, age, and weight. On February 28, 2025, APHA Member 1 received a notice of grant termination from NIH informing them that NIH would be terminating the last year installment of the grant, amounting to $650,000. That notice includes Termination Section 3 (DEI).

136. Because of the termination, the study team, who were expecting to be employed until January 2026, have lost job security, and they cannot complete analyses of the study's key outcomes—measuring and analyzing the health impacts of discrimination—or share these findings with community health centers and study participants.

137. APHA Member 2 served as principal investigator on a four-year, $6.8 million R24 grant establishing the Coordinating Center for National Pain Scientists ("Coordinating Center") with the purpose of connecting a growing network of nearly 5,000 pain researchers across the country to support collaboration, improve networking, and centralize trainings and educational resources.

138. On March 21, 2025, APHA Member 2 received a notice of grant termination with Termination Section 3 (DEI). APHA Member 2 was alarmed and confused to see funding for the Coordinating Center cut because it does not support any study related to DEI and no hiring or scholarship decisions based on specific demographics have ever been made. To the contrary, the Coordinating Center is open to all researchers studying pain and no demographics have been

prioritized or excluded. The only reason APHA Member 2 can identify for why the grant was terminated is because the original NOFO required the Coordinating Center to include a diversity plan describing how its work would support the biomedical field broadly, including historically underrepresented researchers; however, this was ancillary to its operations and no financial resources have ever been devoted to it.

139. As a result of this termination, four staff members working on the Coordinating Center have been furloughed, APHA Member 2 has lost nearly all of their salary, and approximately $1 million may now be wasted on pre-obligated spending toward an annual conference that can no longer occur. Without the Coordinating Center, fewer pain researchers will be trained to address chronic pain, and public health is harmed due to the reduced knowledge about how to treat and manage pain without running the risk of addiction.

140. APHA Member 3 has had one grant terminated for which they are principal investigator, and three other grants terminated for which they are a co-investigator, including an R01 grant for a longitudinal study aimed at developing interventions to reduce drug use and promote mental and physical health in Black men. On March 20, 2025, with only five weeks left to complete this multi-year project, NIH canceled the grant, effective immediately, with a termination letter that includes Termination Section 3 (DEI).

141. Due to the termination, APHA Member 3 has to wrap up a multi-year project five weeks early, and is unable to compensate three research team members who had already performed work on the project but had not yet submitted invoices for their hours worked. Collectively, these research assistants are owed compensation for their work on the grant for roughly 130 hours, an estimated $8,560.

142. APHA Member 4 has had NIH terminate five grants that support their research, including an approximately $4 million grant for a randomized controlled trial with 375 participants using peer intervention to encourage the use of PrEP in order to address high rates of HIV in transgender men who have sex with men. On March 21, 2025, NIH terminated the grant through a notice including Termination Section 1 (Gender Identity).

143. The impacts of the grant termination are severe. APHA Member 4 cannot pay their staff of six, has lost three months of their own salary, and will be restricted in their ability to work on a project that took years to develop and fund.

144. NIH has terminated three grants supporting APHA Member 5's research, including an R01 grant aimed to develop new or modified caregiving measures for the nearly one million sexual and gender minority adults in the U.S. who are caregivers and to ensure that they are included in future research on caregiving for those with Alzheimer's disease. On March 21, 2025, NIH terminated this grant with a notice that includes Termination Section 1 (Gender Identity).

145. The impacts of the grant termination are dire. APHA Member 5 has lost much of their salary and is in the process of laying off their staff of at least 35 people, and their co-investigators are doing the same. Beyond that, sudden termination of the study has broken the trust of the participants in the study—all LGBTQ caregivers for people with Alzheimer's who had each spent two years answering questions about their caregiving experiences for research that will now not be completed.

146. NIH has also unlawfully terminated grants supporting the work of APHA Members 6 and 7, both principal investigators on a five-year, $2.45 million Kirschtein-NRSA T32 grant funding recruitment and training of postdoctoral scientists. The program increases the pipeline of scientists studying addiction and related conditions and provides training in treatments that reduce

overdose deaths by 50%, work critical to HHS priorities to address the opioid crisis. Consistent with the NOFO's listed purpose to ensure a "diverse and highly trained workforce," their grant proposal prioritized recruitment of postdoctoral fellows from groups excluded based on race and ethnicity, people with a disability, people who are LGBT+, people having a disadvantaged background, and those with "diverse training backgrounds." However, despite this intention, of the four offers made to postdoctoral trainees for acceptance into the training program to date, all four were made to white candidates. On March 21, 2025, before the conclusion of the first-year budget period, the APHA members received a notice that their grant was terminated including Termination Section 3 (DEI).

147. As a result of the grant termination, APHA Members 6 and 7 have rescinded offers to postdoctoral fellows for entry into the training program. Fewer clinical researchers will be trained to address substance abuse, and trainees will not be able to pursue scientific inquiries that could have led to novel non-pharmacological approaches to reducing the risk of substance use disorders.

148. APHA Member 8 is a postdoctoral fellow who had been in the first year of the three-year training program. The sudden withdrawal of the T32 grant funding has enormous consequences for their career path. The termination, at a time when the application period for most other T32 grants has ended, means they will be without employment in academia until at least July 2026.

149. NIH has terminated at least two grants that support the research of APHA Member 9, totaling approximately $3 million, to better understand efforts that could promote HIV prevention and treatment, and to address health inequity experienced by gay, elderly, and racial

minority populations and populations living with or without HIV. The grants were terminated in March using a notice of termination that includes Termination Section 3 (DEI).

150. Due to the grant terminations, APHA Member 9 will likely have to lay off at least three staff members, will lose approximately 20% of their annual salary, and will have to conclude the study before completing sufficient recruitment to achieve the sample size needed to conduct valid—and meaningful—statistical analyses. Cutting off these studies will prevent their contribution to the understanding of HIV and comorbidities (e.g., heart attacks, diabetes, or mental illness) across racial groups.

151. APHA Members 10 and 11 were awarded an R15 grant for over $450,000 in support of their research on ways to improve healing for sexual and gender minority survivors of sexual violence, given the high rates of sexual violence they experience, and creating opportunities to train student researchers. In March, within the first year of the three-year grant, they received a notice of grant termination from NIH including Termination Section 1 (Gender Identity). Tied to this R15 grant was an application for a diversity supplement of approximately $162,000 to support an early career trainee on the research team that has been in limbo for the last three months.

152. As a result of the grant termination, these APHA members will not have funds to pay their students and will lose a quarter of their own salaries. Nor will they be able to realize the project's aim of training people to better respond when a sexual or gender minority discloses that they have been a victim of sexual violence.

153. APHA Member 12 received a 4.75-year, $3.4 million R01 Research Project Grant from NIH to fund their research on stigma around HIV testing and PrEP use among U.S. Latino men who have sex with men. On March 20, 2025, only about 40 days before the project's end date, the member received a notice that the grant was terminated. The grant termination notice includes

Termination Section 3 (DEI). Since not all participants completed interviews, it is impossible to complete the project's longitudinal analyses.

154. As a result of the grant termination, almost $3,300,000 in sunk costs on the project have been wasted, two individuals hired to interview participants have already had their employment terminated, additional project team members may imminently lose their jobs and the 503 participants in the study will be harmed when they learn that the grant has been terminated, as it will create further stigma.

155. APHA Member 13 was awarded an almost five-year, $1,487,916 International Research Training Grant from NIH funding the Malaysian Implementation Science Training program at the University of Malaya in collaboration with Yale University, a first of its kind initiative designed to address Malaysia's rapidly expanding HIV epidemic through training University of Malaya faculty and early career researchers.

156. On March 21, 2025, in the fifth year of a five-year grant, the lead investigator received a notice that the grant was terminated. The grant termination notice includes Termination Section 1 (Gender Identity). A renewal of the grant was recently reviewed and received a highly competitive score that should have committed five years of continued funding; this will no longer happen.

157. APHA Member 14 received a two-year, $428,270 R25 (research training and career development) award to fund training and mentorship of early-stage investigators on measurement rigor and ethical practices. The program's goal is to narrow the gap in research on perinatal intimate partner violence, which has marked effects on maternal health outcomes. It was proposed in response to a funding call for projects addressing intimate partner violence and intended to contribute to the NIH Implementing a Maternal Health and Pregnancy Outcomes Vision for

Everyone Initiative, launched in 2019 in response to high rates of pregnancy-related complications and deaths in the United States.

158. On March 21, 2025, before the conclusion of the first-year budget period, APHA Member 14 received a notice that the award was terminated. The termination letter includes Termination Section 3 (DEI). As a result of the award termination, APHA Member 14 incurred over $50,000 in sunk costs on the project and forfeited valuable training and research outcomes. APHA Member 14 and another APHA Member working on the project may lose their jobs, as both positions are grant-funded.

159. APHA Member 15 received a three-year, Kirschstein-NRSA fellowship aimed to develop and implement Rapid Start ART, an HIV treatment prescribed immediately after diagnosis. The fellowship's training component includes coursework, mentorship, and research on stigma, implementation science, and dyadic analysis. The fellowship bridges the gap between being a doctoral student and a professor. On March 18, 2025, only about a month after the project began, the member received a notice that the grant was terminated. The termination letter includes Termination Section 2 (DEI). Only a few hundred dollars of the grant funding had been withdrawn; the member has not yet received a paycheck. However, the member had already begun significant planning for the three-year grant, completing paperwork and meeting with the data collection team. The member had recently moved to live near the university and may lose their job.

3. Plaintiff Ibis

160. In September 2023, Plaintiff Ibis was awarded a 5-year R01 research grant, with approximately $500,000 in funding per year for a project to study methods for improving the collection and quality of data in sexual and reproductive health research for people including those who identify as transgender and gender diverse. Plaintiff Ibis had applied for the grant two years

before that and scored in the top two percent of applications submitted. After years of developing and testing the survey methods, and on the eve of launch, Plaintiff Ibis received a termination notice from NIH in March 2025 using Termination Section 2 (Gender Identity). Even though the research supported by the grant specifically advances the priorities of NIH's National Institute of Child Health and Human Development, NIH terminated the grant for purportedly "no longer effectuat[ing] agency priorities."

161. As a result of the grant termination, Plaintiff Ibis must restructure research teams because of staffing pressures and seek additional funding to cover the salaries of four employees staffed on the project. Plaintiff Ibis has also had to pause the next phase of the study, hindering collection of crucial data on sexual and reproductive health experiences and preferences from under-studied populations.

K. NIH's Refusal to Consider Individual Plaintiffs' and Associational Members' Pending Grants, Extensions and Renewals of Existing Grants, and Stop Work Orders

162. Pursuant to the Directives, NIH is refusing to consider pending Pipeline Grant applications that it deems DEI-related.

1. Plaintiff Maphis

163. Plaintiff Maphis's MOSAIC application is one such grant. On November 12, 2024, Dr. Maphis applied for a MOSAIC grant, intended to help diversify the profession. Her proposed research would, if funded, study the link between Alcohol Use Disorder and Alzheimer's Disease. It would provide five years of funding and help her transition from her mentored postdoctoral research position at the University of New Mexico to a junior faculty member elsewhere. It would have, in short, helped launch her career as an independent researcher.

164. Dr. Maphis's application was assigned to a study group scheduled to score her proposal on March 4, 2025. The morning of March 4, however, she learned that her proposal had

been reassigned to a new generic group that was not scheduled to meet. Later that day NIH notified her that her proposal, along with others, had been pulled from its original study group. When Dr. Maphis asked whether her proposal would be reviewed, she was told "unfortunately not." Dr. Maphis was told by a member of her original study group, which had reviewed her application before March 4, that her application was highly regarded and likely would have received funding had it not been for NIH's changes. Dr. Maphis's current funding expires on September 30, 2025. Without additional funding, which the MOSAIC award would have provided, she will lose her job. She will also lose out on the training she would have received from the MOSAIC program. As a consequence, Dr. Maphis will be less competitive on the faculty job market, unlikely to secure a faculty position, and potentially forced to abandon a career in academia, which she has been training for and working towards for the last 17 years.

2. Plaintiff APHA Members

165. APHA Member 16, who researches zinc's impact on health, is the recipient of a MOSAIC grant. Member 16 has recently completed the two year (post-doctoral training) K portion of the grant and was slated to transition to the R portion of the grant, in which NIH would fund the first three years of their position as a tenure-track Assistant Professor. APHA Member 16 began their faculty position in January but never received their NOA for the R portion, which normally would have been received in January or February.

166. APHA Member 16 has not been getting responses from NIH about the status of their application, which is particularly concerning for APHA Member 16 because NIH has cancelled the MOSAIC program, removed it from the National Institute of General Medical Sciences website, and terminated the NOFO early. As a result of not receiving the NOA, APHA

Member 16 has not been able to obtain the necessary funding for completing their lab setup, hiring staff, and continuing this important research.

3. Plaintiff UAW Members

167. UAW Member 1, a PhD candidate at a private university in California, submitted an F31 dissertation proposal that, if funded, would help inform intervention efforts for suicide prevention among LGBTQ youth experiencing homelessness—the leading cause of death for this population. They received a high score (14th percentile) on the proposal. However, they learned the project would likely not be funded because of new restrictions on LGBTQ research. This will harm UAW Member 1's ability to progress through their PhD program.

168. UAW Member 2, a postdoctoral researcher at a private university in New York, has a pending application for an NIH Diversity Supplement. They research affect, sleep, and processes of embodied change (sleep health). They have received no updates from NIH on their application. Without this funding opportunity, they cannot remain at their university to complete their program. They will have to stop ongoing projects and forfeit the rest of a supplemental grant they received because they will no longer have institutional support. They will have to apply for new postdoctoral positions elsewhere that would require them to change their project and lose the research investments they have already made. This will make them less competitive for the next step of their research career and require they spend longer as a postdoctoral scholar, earning a salary as much as $25,000 lower than they would have had they remained at their current institution.

169. As a result of NIH's refusal to consider their application, UAW Member 2 is in the position of having to choose between leaving their career as an academic researcher, for which they have trained for over 10 years, or moving to a position in a different part of the country or outside the country, away from their family, their partner, and the medical care they need as a

person with a physical disability. If they do not find an alternative position, they face a period of unemployment in one of the most expensive cities in the world.

170. UAW Member 3, a postdoctoral researcher at a private university in New York, applied to the MOSAIC K99 program through the National Institute of General Medical Sciences. This five-year career transition award of $1 million would launch their career studying mechanisms of behavior (evolution of behavior). Their proposal received an impact score of 10 (a perfect score) last fall. NIH, however, will no longer communicate with UAW Member 3 about this award. UAW Member 3 has aged out of eligibility for the main K99, so reapplying is not an option for them. Because they thought they had secured the MOSAIC K99 award, UAW Member 3 did not apply to the Simons Foundation Fellows-to-Faculty Award. Without the K99 award, UAW Member 3 is in a strained financial position to finish their postdoctoral studies and will be much less competitive on the job market.

171. UAW Member 4 is a graduate student at a private university in New York, where they research neurophysiology, in particular, the neurobiological mechanisms underlying maternal caregiving. They were awarded a transition grant known as a D-SPAN (F99/K00) intended to support a defined pathway across career stages for outstanding graduate students from diverse backgrounds, including those from groups that are underrepresented in neuroscience research.

172. Despite having received a NOA for this program, their NIH program officer has since encouraged them to apply for other funding programs, citing uncertainty surrounding the future of the funding program. Consistent with this messaging, UAW Member 4 also noticed that language on the D-SPAN program website has changed, now referring to the D-SPAN grant in the past tense, and the pictures and bios of previous and current awardees have been removed. UAW

Member 4's potential lack of funding has created significant challenges for them in securing a postdoctoral position.

173. UAW Member 5 is a graduate student worker at a private university in California. They applied for a two-year NIH Diversity Supplement to an existing R01 grant. This supplement is intended to support underrepresented researchers, with the goal of expanding UAW Member 5's skillset and substantiating their potential to become a productive investigator. The project was part of a multi-university collaboration and would fund the bulk of UAW Member 5's dissertation research, covering direct and indirect costs, materials and supplies, travel, and other essentials.

174. UAW Member 5 completed the application process and corresponded with NIH coordinators, understanding that the supplement was officially under review. However, on the day Executive Order 14151 was announced, all communication ceased. The NIH website pages related to the diversity supplement were scrubbed, and the coordinators became unreachable. No formal notice of cancellation or termination was ever provided—only a sudden disappearance of any evidence that the supplement application existed. To date, UAW Member 5 is left to assume that the grant as a whole no longer exists, despite never receiving any official update regarding its status while under review and with no clarity on how to proceed.

175. UAW Member 6 is a postdoctoral student at a private university in New York and a MOSAIC K99/R00 scholar whose grant studies how social cues guide emotions. This study was motivated by the need to understand how social processing is impaired in several neuropsychiatric disorders. UAW Member 6 had begun the process of requesting a no-cost extension but has been unable to communicate with the NIH program officer since January 2025 to begin this process. UAW Member 6 was well-situated to receive this grant given their extensive service in mentoring

and advocacy while simultaneously performing high-quality science—a feat not many scientists successfully undertake.

176. UAW Member 6 is relying on the R00 portion of their MOSAIC grant to kickstart their tenure-track faculty lab and to continue and expand on their work to develop novel treatments for psychiatric disorders. Given NIH's complete silence, UAW Member 6 fears they will not receive their R00 when they apply for it in this year's upcoming job cycle, which could potentially restrict their nation-wide job search. This has caused immense stress and has created uncertainty in their research career progression in securing a tenure-track faculty position.

177. UAW Member 7, a graduate student at a private university in New York, was preparing an F31 parent grant proposal to study the impacts of anti-transgender structural stigma (anti-transgender legislation). That funding opportunity, however, was cancelled as of March 10, 2025, depriving UAW Member 7 of the potential funding that grant would have provided.

178. UAW Member 8, a graduate student at a private university in New York, sought an F31 Diversity grant to study developmental neurobiology. This research is crucial to gain insight into early risk factors of neurodevelopmental and psychiatric disease and enable the identification of timepoints for effective prevention and treatment. UAW Member 8's proposal was highly scored (Impact score: 18, Percentile: 2.0) and, accordingly, NIH issued a notice of award in August 2024. Their supervisor, however, was notified in March 2025 that F31 had been cancelled. UAW Member 8's application status has since been changed to "pending" and the budget period has been significantly shortened from the initial accepted budget period. NIH's decision to cancel this grant will hinder development on learning the neurodevelopmental factors preceding psychiatric disease onset, which is relevant to nearly half of the U.S. population. The lack of funding will also undermine UAW Member 8's ability to progress through their PhD program.

179. UAW Pre-Member 1 is a postdoctoral fellow at a private university in Massachusetts and has been awarded a MOSAIC K99/R00 fellowship.[93] They are finishing the K99 phase of the award. They study how cells respond to signals outside the cell. By better understanding how this process is dysregulated, UAW Pre-Member 1 hopes to improve cancer therapeutic strategies in the future.

180. As is standard for K99/R00 fellows, UAW Pre-Member 1 has been planning to apply to activate their R00 funding this summer, once they have found an independent position as an assistant professor. They have discussed this plan with their NIH program officer. This should be a routine process, as the scientific component has already been evaluated and positively reviewed. However, the status of the MOSAIC program has become unclear—the website has been deleted, and the program is not seeking new applicants.

181. UAW Pre-Member 1 has been unable to get information from NIH about their ability to activate the R00 funding. They fear, like other MOSAIC scholars, that their grant will be terminated. These changes to NIH policy have created uncertainty in UAW Pre-Member 1's transition to an independent position. Not having this award would significantly weaken their ability to negotiate a job offer and impair their ability to begin an independent lab.

182. UAW Pre-Member 2 is a postdoctoral scholar at a private university in Pennsylvania, where they are tracking outbreaks of newly emerging multi-drug-resistant pathogens and investigating new ways to treat and prevent infections. They are funded by an NIH K12 training and career development grant awarded to their home institution which has a stated goal of improving diversity, equity, and inclusion in the biomedical sciences. As part of their

[93] "Pre-member" means UAW is their exclusive bargaining representative in ongoing negotiations with their employer and that they intend to become dues-paying members once a collective bargaining agreement is in place.

training under this grant, they also taught science classes at minority-serving colleges and universities in their metropolitan area.

183. When UAW Pre-Member 2 was accepted into this postdoctoral training program, they were told the tenure of the program was three years. Since January 21, 2025, however, they have been told that the status of their funding in the near future is unknown. The principal investigators of the training grant at their home institution have been unable to reach the assigned program officer, and they do not know whether the regularly anticipated non-competing renewal will be completed this summer.

184. To UAW Pre-Member 2's knowledge, there has been no communication from the federal government about the status of this entire category of training grants, nor of individual grants in this funding category. As a result, UAW Pre-Member 2 does not know whether they will lose their funding in the next few months. UAW Pre-Member 2 chose this funding path because they want to research infectious disease that directly informs clinical outcomes, and because they want to educate future generations of biomedical researchers. They had planned to spend three years developing an infectious disease research program which they could bring to a faculty position. Now, this future is uncertain as their research training time may be cut short by 30%.

185. UAW Pre-Member 3 is a third-year graduate student in the Cell and Molecular Biology Ph.D. program at a private university in Pennsylvania. They are currently performing a research project that seeks to understand how heterochromatin associated proteins impede changes to cell fate and how mutations in these proteins lead to defects in neuronal development. They applied for the F31 Diversity grant on December 8, 2024. On February 13, 2025, their proposal was assigned to the Molecular and Cellular Sciences and Technologies ZRG1 F05-A (20) study section, scheduled for review on March 26–27, 2025. However, on March 12, 2025, UAW Pre-

Member 3 was informed that the study section information had been removed from their proposal's status. To date, the NIH has not provided any clarification or a timeline regarding when—or even if—the application will be reviewed.

186. This change is particularly perplexing given that the only difference between the standard F31 and the F31 Diversity grant is the inclusion of an additional statement recognizing that the applicant comes from an underrepresented community in the sciences. For early-career scientists, obtaining such grants does more than support a research project financially; it represents recognition of their dedication, hard work, and potential to become future primary investigators.

187. UAW Pre-Member 4 is a postdoctoral associate at a private university in New York. They applied for a diversity supplement for a project grant that seeks to improve transport of protective antibodies from mother to child during Cytomegalovirus infection. The study was motivated by the idea that Cytomegalovirus infection could prevent this transfer, leaving neonates vulnerable to a variety of congenital infections in utero.

188. UAW Pre-Member 4 met the supplement's DEI requirements as a first-generation college student and a Latina. As of January 2025, the proposal was under review. However, the funding mechanism was abruptly cancelled due to its DEI requirements. This has been a significant setback for UAW Pre-Member 4 as a first-year postdoctoral student, as the supplement would support the majority of their postdoctoral salary. The lack of funding is a barrier to the start of this project and is delaying their expected timeline for gaining independence as a scientific investigator.

189. The cancellation of this funding mechanism robs the field of study of diverse perspectives and ideas. Ultimately, restricting access to funding for researchers from diverse backgrounds will limit the impact that academic institutions can make to biomedical research.

190. UAW Pre-Member 5 is a postdoctoral research scholar at a private university in Pennsylvania. They are working on their K99/R00 "Pathway to Independence Award" from the Helping to End Addiction Long term ("HEAL") Initiative—a program co-sponsored by the National Institutes of Mental Health and the National Institute of Drug Abuse. This five-year, approximately 1 million dollar grant provides two years of advanced postdoctoral training followed by three years of start-up funds for an investigator to begin an academic lab. One of the goals of the HEAL initiative is to develop new medicines to treat pain without propensity to cause addiction, an issue of great importance to the opioid crisis.

191. On March 10, 2025, UAW Pre-Member 5 was made aware that the Request for Applications (RFA) RFA-NS-22-025 (which contained a diversity component), had been eliminated. This was not communicated by NIH. The program was designed to allow applicants from disadvantaged backgrounds to apply for evaluation in smaller study sections. UAW Pre-Member 5 was raised in an American "rust belt" city that has long struggled with the opioid epidemic. The cancellation of NIH's interest in diversity means that UAW Pre-Member 5 will be competing against a larger applicant pool, which limits their chance of success in an already competitive grant mechanism.

192. UAW Pre-Member 6, a graduate student at a private university in Pennsylvania, studies the replication mechanisms of viral diseases spread by mosquitoes to identify targets for drug therapeutics. They sought this course of study because of the lack of existing or approved vaccines and antivirals to counter viral disease in humans. A warming climate has also increased the geographic spread of these diseases as a consequence of a broader habitat for mosquitos. UAW Pre-Member 6 applied to the F31 Diversity Fellowship for the August 2024 deadline. After receiving a score and percentile well within the fundable range in December 2024, UAW Pre-

Member 6 and their principal investigator waited for a just in time request for information from NIH and notice of award. However, after NIH funding freezes were announced in January 2025, UAW Pre-Member 6's study section was canceled.

193. On March 18, 2025, UAW Pre-Member 6 reached out to their assigned NIH program officer to ask about the status of their application. The program officer then informed UAW Pre-Member 6 that their grant had been terminated. The award would have funded UAW Pre- Member 6 and their principal investigator for three years, covering stipends, conference travel, and materials for their project.

194. Completing an F31 grant application is excellent practice for the development of scientific writing and project presentation. Aside from this, the Diversity F31 is built to uplift minority researchers through financial support. Although other grant pathways exist, this grant gave UAW Pre-Member 6 the opportunity to showcase a broader part of their identity that can enhance their scientific research. Part of the F31 Diversity application process is writing about how you plan to uplift other scientists. For UAW Pre-Member 6, the cancellation of diversity fellowships feels like a devaluation of their scientific research and of their sense of self as a scientist. Funding may still be provided by their lab, but the termination of the grant has, to their knowledge, caused the principal investigator to limit expenditure of funds, including conference travel and reagent purchase, which affects UAW Pre-Member 6's ability to carry out their research, gain experience presenting their work, and network with other scientists.

CAUSES OF ACTION

195. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

COUNT I
Violation of the Administrative Procedure Act – Arbitrary and Capricious

196. The APA provides that courts "shall . . . hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

197. Agency action is arbitrary and capricious if the agency has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

198. Defendants are acting in an arbitrary and capricious manner in violation of the APA.

A. Grant Terminations

199. Individual Plaintiffs, Plaintiff Ibis, and members of Associational Plaintiffs' members whose grants have been terminated ("Terminated Plaintiffs") assert this portion of this cause of action against all Defendants.

200. NIH's grant terminations pursuant to the Directives constitute final agency action under the APA for which there is no other adequate remedy in a court.

201. These terminations are arbitrary and capricious for at least seven reasons.

202. First, in its termination letters, NIH fails to provide adequate reasoning explaining how these studies fall below the agency's standards for scientific research. NIH's repetition of boilerplate and conclusory language across all the termination letters is not an adequate explanation as to how any specific study fails to meet agency priorities.

203. Second, NIH fails to analyze any relevant data. The termination letters show that NIH did not consider individual, or any, data from the grants at issue or from any body of research that would contradict the value or rigor of the grants at issue.

204. Third, NIH is not providing a reasoned explanation for its actions, as it is ignoring reliance interests. In the termination letters, NIH fails to mention, and does not appear to have considered, how these terminations will affect the reliance interests of researchers (including Plaintiffs), the institutions that host them, the participants in the terminated studies, and the body of research furthered by the terminated grants and the populations who would have benefitted from that research.

205. Fourth, NIH relies on assertions contrary to its prior award review and policies, including the NIH Strategic Plan and IC Strategic Plans. NIH states that its terminations are based on an alleged change in priorities, but NIH has neither adopted, described, nor explained any new priorities, and the strategic plans under which the previous awards were made remain in effect.

206. Fifth, the terminations run counter to available evidence and reflect NIH's failure to consider important aspects of the problems addressed by the terminated grants and the areas of research mandated by, among other things, Congress, NIH's Strategic Plan, and NIH's policy guidelines. As its stated change in priorities runs directly counter to congressional mandates, NIH is also relying on factors that Congress does not intend for NIH to consider.

207. Sixth, NIH reliance on mandates by individuals outside the agency (including, for example, from DOGE individuals who drafted some number of the termination letters at issue), violates NIH's requirement to appropriately reach its own decision.

208. Seventh, an agency acts arbitrarily and capriciously if it acts in a manner that is contrary to its own regulations or a congressional statute. For the reasons expressed in Counts II, III, and IV, Defendants have acted contrary to their own regulations or congressional statutes.

209. For those and other reasons consistent with the allegations herein, Defendants' grant terminations are arbitrary and capricious in violation of the APA. 5 U.S.C. § 706(2)(A).

B. Refusal to Consider Applications

210. Individual Plaintiffs, Plaintiffs Ibis, and Associational Plaintiffs' members whose grant applications NIH has refused to consider pursuant to the Directives ("Applicant Plaintiffs") assert this portion of this cause of action against all Defendants.

211. NIH's refusal to consider applications for published NOFOs that Defendants subsequently removed from publication constitutes final agency action under the APA.

212. For the same reasons described above, NIH's refusal to consider properly submitted applications is arbitrary and capricious. That is, NIH (i) failed to adequately explain its reasons for this refusal; (ii) failed to analyze any relevant data; (iii) failed to consider reliance interests; (iv) has purported to rely on a change in priorities that has not occurred and that it has not explained; (v) failed to consider important aspects of the mandated areas of research addressed by the proposed grants and considered factors that Congress did not intend for it to consider; (vi) failed to appropriately reach its own decision; and (vii) acted contrary to its own regulations or congressional statute.

C. The Directives

213. All Plaintiffs assert this cause of action against all Defendants.

214. NIH's adoption of the Directives is final agency action under the APA.

215. For the same reasons described above, NIH's adoption of the Directives is arbitrary and capricious. That is, NIH (i) failed to adequately explain its reasons for the adoption of the Directives; (ii) failed to analyze any relevant data; (iii) failed to consider reliance interests; (iv) has purported to rely on a change in priorities that has not occurred and that it has not explained; (v) failed to consider important aspects of the mandated areas of research addressed by the Directives and considered factors that Congress did not intend for it to consider; (vi) failed to appropriately reach its own decision; and (vii) acted contrary to its own regulations or congressional statute.

COUNT II
Violation of the Administrative Procedure Act – Not in Accordance with Law

216. Terminated Plaintiffs assert this cause of action against all Defendants.

217. The APA directs courts to hold unlawful and set aside agency actions that are not in accordance with law. 5 U.S.C. § 706(2)(A). Defendants fail to meet this standard in at least three ways.

218. First, Defendants are purporting to terminate grants based on 2 C.F.R. § 200.340(a)(2) (2020), which allowed termination if an award "no longer effectuates the program goals or agency priorities." However, HHS did not adopt OMB guidance allowing for termination under 2 CFR Part 200.340 based on changes to agency priorities until October 2024, with an *effective date of October 1, 2025*. In the revised NOAs that NIH sent to Plaintiffs when it terminated their grants, NIH states that its action is "in accordance with 2 CFR § 200.340 as implemented in NIH GPS Section 8.5.2." But NIH Grants Policy Statement Section 8.5.2 did not implement the revised 2020 version of 2 CFR 200.340 because HHS did not implement that revised version in its regulations. This section purports "to be compliant with governing statutes

and the requirements of 2 CFR Part 200, *as modified by previously approved waivers and deviations*. However, in the case of a conflict, the statutes and regulations govern."[94]

219. Second, even if 2 C.F.R. § 200.340(a)(2) (2020) applies, NIH's grant terminations are not in accordance with that regulation. 2 C.F.R. § 200.340(a)(2) (2020) provided that a federal award may be terminated in part or in its entirety "to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities." For the reasons stated in the preceding paragraph, NIH's termination was not "authorized by law." In addition, for the reasons already discussed in Count I (Arbitrary and Capricious), NIH's termination decisions were not consistent with the requirements of the APA—and therefore beyond "the extent authorized by law."[95]

220. Further, the guidance accompanying the regulation indicates that any termination pursuant to 2 C.F.R. § 200.340(a)(2) must be based on the agency's consideration of evidence—and in particular, "additional evidence"—indicating that the "award no longer effectuates the program goals or agency priorities." *See* Guidance for Grants and Agreements, 85 FR 49506, 49507 (2020). But as already alleged, NIH's terminations are not based on *any* evidence regarding the specific grants.

221. Moreover, 2 C.F.R. § 200.340(b) (2020) stated that the agency "should clearly and unambiguously specify termination provisions applicable to each Federal award, in applicable regulations or in the award, consistent with this section." Likewise, the OMB Uniform Guidance that NIH recently adopted to go into effect October 1, 2025 only allows for termination based on changes to agency priorities "pursuant to the terms and conditions of the Federal award," and states that the agency "must clearly and unambiguously specify all termination provisions in the terms

[94] *See* Nat'l Insts. of Health, *NIH Grants Pol'y Statement* § 3 (Apr. 2024) (emphasis added).
[95] *See* 2 C.F.R. § 200.340(a)(2) (2020).

and conditions of the Federal award."[96] Yet the original NOAs that Plaintiffs received did not include reference to the OMB Uniform Guidance and did not state that an award could be terminated for shifting agency priorities.

222. Third, the terminations are not in accordance with the terms of the pertinent NIH Grants Policy Statements. Section 8.5.2 allows involuntary termination solely "if a recipient has failed to comply with the terms and conditions of award." Across its termination notices, NIH has acknowledged that it "generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision," in accordance with the respective NIH Grants Policy Statement governing each award. While "NIH may immediately terminate a grant when necessary," "when necessary" is cabined by reference to circumstances "such as to protect the public health and welfare from the effects of a serious deficiency" and is only allowed under the limited circumstance where "a recipient has failed to comply with the terms and conditions of award."

223. NIH has failed to show that termination of any grants pursuant to the Directives met those circumstances. Defendants have not based termination of Plaintiffs' grants on a failure to comply with the terms and conditions of their awards. Even if termination were available to NIH where a grantee has met the terms and conditions of their award, NIH has failed to abide by its obligation under the NIH Grants Policy Statements to allow those grant recipients an opportunity to take appropriate corrective action before NIH terminated their grants.

224. Fourth, for the same reasons expressed below in Count III (APA – Exceeds Statutory Authority), Defendants' actions pursuant to the Directives—including the grant

[96] 2 CFR 200.340(a)(4),(b) (2024).

terminations and refusal to review submitted grant applications—run afoul of the mandates set forth by Congress.

225. Thus, Defendants failed to act in accordance with law in violation of the APA. 5 U.S.C. § 706(2)(A).

COUNT III
Violation of the Administrative Procedure Act – Exceeds Statutory Authority

226. All Plaintiffs assert this cause of action against all Defendants.

227. A reviewing court must hold unlawful and set aside agency actions that are found to be "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

228. Through Section 301(a) of the Public Health Service Act, *see* 42 U.S.C. § 241(a), Congress delegated authority to NIH to "make grants-in-aid to universities" and other research institutions for the purpose of "promot[ing] the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." *Id.*

229. In addition, Congress has mandated the expenditure of funds by NIH and ICs to promote health equity across health disparity populations, including racial and ethnic minority populations, less privileged socioeconomic status populations, underserved rural populations, sexual and gender minorities, and any subpopulations that that can be characterized by two or more of these descriptions. Among those statutory mandates are:

a. 42 U.S.C. § 281(b)(24), which created the National Institute on Minority Health and Health Disparities to "conduct and support…research, training, dissemination of information, and other programs with respect to minority health and conditions and other populations with health disparities." *Id.* at § 285t(a).

b. 42 U.S.C. § 285t, which mandates that the Director of the National Institute on Minority Health and Health Disparities "shall[,] in expending amounts appropriated under this subpart give priority to conducting and supporting minority health disparities research," and "ensure that the plan and budget serve as a broad, binding statement of policies regarding minority health disparities research and other health disparities research activities…" *Id.* at § 285t(b); (f)(1)(G).

c. 42 U.S.C. § 282(b)(8)(D)(ii), which requires the Secretary, acting through the Director of NIH, to ensure that each of the ICs within NIH "utilize diverse study populations, with specific consideration to biological, social, and other determinants of health that contribute to health disparities."

d. 42 U.S.C. § 282(h), which mandates that "[t]he Secretary, acting through the Director of NIH…, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research."

e. 42 U.S.C. § 282(m), which requires NIH to develop a strategic plan that, among other things, "shall…(B) consider…(iii) biological, social, and other determinants of health that contribute to health disparities…" *Id.* at § 282(m)(1),(2). The Director of NIH must "ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans." *Id.* at §282(b)(6).

f. 42 U.S.C. § 283p, which mandates that "the Director of the National Institutes of Health shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations."

g. 42 U.S.C. § 283*o*(b)(2) which requires the Director of NIH to "develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to…enhance workforce diversity."

230. Those mandates, and NIH's policies and regulations to effectuate them, apply to the funding and review of both Project-Based Grants and Pipeline Grants.

231. But Defendants' actions pursuant to the Directives—including the grant terminations and refusal to review submitted grant applications—run afoul of those statutory mandates.

232. Accordingly, Defendants acted "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

COUNT IV
Violation of Administrative Procedure Act – Contrary to Constitutional Right

233. All Plaintiffs assert this cause of action against all Defendants.

234. A reviewing court must "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

235. Defendants' grant terminations and refusal to consider grant applications constitute final agency actions under the APA.

236. For the reasons described in Count VI (Void for Vagueness), Defendants' actions are contrary to constitutional rights, and the Court must hold them unlawful and set them aside.

COUNT V
Violation of the Administrative Procedure Act –
Unlawfully Withheld, Unreasonable Delay, or Failing to Conclude Matter Presented

237. Applicant Plaintiffs assert this cause of action against all Defendants.

238. An agency must "proceed to conclude a matter presented to it," 5 U.S.C. § 555(b); accordingly, a reviewing court must "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

239. Defendants' refusal to consider submitted grant applications pursuant to the Directives constitutes final agency actions under the APA.

240. Defendants' consideration of applications for Pipeline Grants has been unlawfully withheld or unreasonably delayed for the following reasons: (i) HHS regulations require NIH to accept, disapprove, or "defer because of either lack of funds or a need for further evaluation"; (ii) NIH policy requires that it consider each application submitted to it and does not allow the agency to withhold consideration of applications based on changes in agency priorities; (iii) large numbers of current and future biomedical researchers risk unexpected job loss that will harm not only them personally but also the development of biomedical research generally; and (iv) the applications' proposed research is essential to public health, making delays in this sphere less tolerable than in other spheres such as economic regulations. Thus, the Court must compel the agency to consider these applications.

COUNT VI
Violation of the Fifth Amendment – Void for Vagueness

241. Terminated Plaintiffs assert this cause of action against all Defendants.

242. Under the Fifth Amendment to the United States Constitution, a government enactment is unconstitutionally vague if it fails to provide a reasonable opportunity to know what conduct is prohibited or is so indefinite as to allow arbitrary and discriminatory enforcement.

243. Defendants' Directives are filled with vague language that do not give clear notice of what is covered: prohibiting "DEI research activities," or even "giv[ing] the perception that NIH funds can be used to support these activities" as well as research programs "based primarily on…amorphous equity objectives" or "based on gender identity" or relating to "transgender issues." Likewise, the language of the various scripts in NIH termination notices include many of these same undefined terms: "gender identity"; "so-called diversity, equity, and inclusion ('DEI') studies"; "amorphous equity objectives"; "vaccine hesitancy"; or "COVID-related" matters, for example. The language of these Directives and terminations notices is unconstitutionally vague, depriving grantees of fair notice and encouraging arbitrary and discriminatory enforcement.

244. Because of the vagueness in the language of Defendants' Directives and NIH's chaotic efforts to give effect to those Directives, Plaintiffs are unsure, for example, which areas of study they can pursue, which populations they can focus on as study subjects, what they might argue to appeal grant terminations, and what the demographics of study participants must be. This makes it impossible to determine how to reconfigure future research to stay within the bounds of NIH's newest "priorities."

245. Defendants' Directives and efforts to purge certain research thus violate the Due Process Clause because its termination notices and related documents provide inadequate notice of what types of research it purports to prohibit.

COUNT VII
Violation of Separation of Powers

246. All Plaintiffs assert this cause of action against all Defendants.

247. The Constitution vests exclusive power over federal spending and lawmaking with Congress; the Constitution likewise requires the Executive branch to faithfully execute the law. These distinct roles of the co-equal branches of government are of critical importance, and "the

carefully defined limits on the power of each Branch must not be eroded." *I.N.S. v. Chadha*, 462 U.S. 919, 958 (1983).

248. The Executive Branch has no constitutional power to unilaterally amend or repeal parts of duly elected statutes.

249. Congress has exercised its Article I legislative power to mandate NIH carry out specific functions. Defendants' actions unlawfully usurp congressional legislative authority, including by ignoring and running counter to the mandates outlined in Count III (APA—Excess of Statutory Authority).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

a. Declare that the Directives—including the February 28 Guidance and March 25 Guidance—and Defendants' other actions to implement the Directives are unlawful and unconstitutional;

b. Declare that NIH's termination of grants pursuant to the Directives, beginning on February 28, 2025, is unlawful and unconstitutional;

c. Temporarily restrain and/or preliminarily and permanently enjoin Defendants from implementing or enforcing the Directives going forward, including from terminating any grants or withholding review of applications, based on allegedly no longer effectuating agency priorities or; in a manner that this Court has determined is unlawful;

d. Order NIH to restore the grant awards, retroactive to the respective termination date, that NIH has terminated pursuant to the Directives or in a manner this Court has determined is unlawful or unconstitutional, including the grant terminations based on allegedly no longer effectuating agency priorities;

e. Order NIH and all ICs to review all properly submitted applications as required by NIH policy and consistent with priorities set forth in the currently operative NIH-Wide Strategic Plan and the ICs Strategic Plans;

f. Order Defendants to file status reports at regular intervals confirming their compliance with the Court's order(s) and judgment(s) in this case;

g. Enjoin Defendants from imposing any negative consequences on Individual Plaintiffs, Plaintiff Ibis, or Associational Plaintiffs' Members and Pre-Members for involvement in this litigation;

h. Award Plaintiffs' reasonable costs and attorneys' fees; and

i. Issue such other relief as the Court deems proper.

[signatures on following page]

Dated: April 02, 2025

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; STATE OF CALIFORNIA; STATE OF MARYLAND; STATE OF WASHINGTON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF DELAWARE; STATE OF HAWAI'I; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF OREGON; STATE OF RHODE ISLAND; and STATE OF WISCONSIN,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JAYANTA BHATTACHARYA, in his official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; NATIONAL CANCER INSTITUTE; NATIONAL EYE INSTITUTE; NATIONAL HEART, LUNG, AND BLOOD INSTITUTE; NATIONAL HUMAN GENOME RESEARCH INSTITUTE; NATIONAL INSTITUTE ON AGING; NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM; NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING; EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; NATIONAL INSTITUTE

No. 1:25-cv-10814-BEM

ON DEAFNESS AND OTHER COMMUNICATION DISORDERS; NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH; NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; NATIONAL INSTITUTE OF MENTAL HEALTH; NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES; NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE; NATIONAL INSTITUTE OF NURSING RESEARCH; NATIONAL LIBRARY OF MEDICINE; NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES; JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES; NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH; and CENTER FOR SCIENTIFIC REVIEW,

Defendants.

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs the Commonwealth of Massachusetts, the State of California, the State of Maryland, the State of Washington, the State of Arizona; the State of Colorado; the State of Delaware; the State of Hawai‘i, the State of Minnesota; the State of Nevada; the State of New Jersey; the State of New Mexico; the State of New York; the State of Oregon; the State of Rhode Island; and the State of Wisconsin allege as follows:

INTRODUCTION

1. The National Institutes of Health (NIH) is a federal agency responsible for conducting and supporting biomedical research. Widely acknowledged as a "crown jewel" of America's scientific institutions—a characterization the agency's director recently reiterated[1]—NIH is the largest public funder of medical research in the world.

2. NIH has "a long and illustrious history [of] supporting breakthroughs in biology and medicine."[2] NIH scientists pioneered the rubella vaccine, eradicating a disease that, in the 1960s, killed thousands of babies and left thousands more with lifelong disabilities.[3] NIH studies led to the discovery of the BRCA mutation, helping countless Americans reduce their risk of breast and ovarian cancer.[4] And NIH research fueled the development of treatments for HIV and AIDS, transforming what was once a fatal disease into one with a nearly normal life expectancy.[5] These are just a few of many, many examples: over the years, NIH-supported research has had a profound impact on Americans' health and wellbeing. Indeed, it is hard to find a medical breakthrough in recent years that has *not* been assisted—whether directly or indirectly—by NIH.[6]

3. NIH's activities have also contributed to our Nation's economic security and prosperity. Today, the United States is a global leader in the health and life sciences—thanks, in

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[1] Opening Statement of Dr. J. Bhattacharya, S. Comm. on Health, Educ., Lab. & Pensions (March 5, 2025), https://bit.ly/Bhattacharya-Statement.

[2] *Id*.

[3] Lyons M., *IRP Vaccine Research Stretches Back to the NIH's Birth*, NIH Intramural Rsch. Prog. (May 18, 2020), https://irp.nih.gov/blog/post/2020/05/a-long-tradition-of-vaccine-breakthroughs.

[4] *Enhancing Breast and Ovarian Cancer Care: The Discovery of BRCA1 and BRCA2*, Nat'l Cancer Inst. (March 7, 2014), https://www.cancer.gov/research/progress/discovery/brca.

[5] *HIV/AIDS Treatment*, Nat'l Inst. of Allergy & Infectious Disease (Jun. 16, 2020), https://www.niaid.nih.gov/diseases-conditions/hiv-treatment.

[6] *See, e.g.*, Cleary E.G. *et al.*, *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4 JAMA Health Forum, no. 4 (2023) (showing NIH funding contributing to 99.4% of FDA-approved drugs from 2010 to 2019), https://pmc.ncbi.nlm.nih.gov/articles/PMC10148199.

no small part, to NIH. The agency's grants have allowed America to train the next generation of doctors, researchers, and biomedical entrepreneurs. And they have ensured that crucial innovations take place in American institutions—allowing the United States to reap the economic benefits of those discoveries. The numbers speak for themselves: in Fiscal Year 2024 alone, NIH's more than $36 billion in awards spurred more than $94 billion in new economic activity—a return of $2.56 for every $1 invested. These investments supported more than 407,000 jobs across every State and the District of Columbia.

4. That critical work is now in jeopardy. By law, NIH provides much of its support for scientific research and training in the form of grants to outside institutions. Since his inauguration, however, the President has issued a barrage of executive orders prohibiting federal agencies from supporting any initiatives with a perceived nexus to certain subjects he opposes, such as "DEI" and "gender ideology." Taking its cue from the executive orders, defendants have adopted a series of directives that curtail NIH's support for previously advertised funding opportunities and previously awarded grants relating to these and other blacklisted topics.

5. These directives are unlawful—as are defendants' actions in developing, implementing, and enforcing them. Plaintiffs bring this action to seek relief for the immediate harms that defendants and their directives are causing to state research institutions.[7]

6. First, defendants' recent policies and actions violate the Administrative Procedure Act (APA). In promulgating directives that prohibit research into certain politically disfavored subjects, defendants have flouted express statutory and regulatory provisions, including statutory

[7] In recent months, a number of the plaintiff states have brought lawsuits challenging other unlawful policies and decisions that affect NIH grants. *See* Complaint, *Massachusetts v. NIH*, No. 1:25-cv-10338-AK (D. Mass. Feb. 10, 2025) (ECF No. 1) (challenging recent NIH guidance purporting to alter the methodology for calculating "indirect costs"); Complaint, *New York v. Trump*, No. 1:25-cv-39-JJM-PAS (D.R.I. Jan. 28, 2025) (ECF No. 1) (challenging an OMB directive instituting a temporary funding pause across federal agencies). The agency actions at issue in those cases are distinct from the acts and omissions at issue here.

provisions directing NIH to support diversity in the scientific workforce and to promote the health of racial, ethnic, sexual, and gender minorities. In this way, NIH's directives are contrary to law. 5 U.S.C. §706(2)(A), (C). Defendants have also departed from NIH's own prior position on the now-blacklisted topics, without acknowledging—let alone providing "good reasons for"—their change in position. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). And what little reasoning that defendants have offered in support of their new blacklisting directives fails to grapple with relevant considerations and runs counter to the available evidence. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983). For these reasons, defendants' directives are also arbitrary and capricious. 5 U.S.C. §706(2)(A). Defendants' recent actions also violate the APA because they have led to unreasonable and intentional delays in the grant-application process, including cancellation of the "study sections" and "advisory councils" that review and approve requests for NIH funding. Accordingly, defendants have "unlawfully withheld" and "unreasonably delayed" required action. *Id.* §706(1).

7. Second, defendants' policies and actions contravene Spending Clause and other separation-of-powers constraints and constitute *ultra vires* executive action. The Constitution "grants the power of the purse to Congress, not the President." *City & County of San Francisco v. Trump*, 897 F.3d 1225, 1231 (9th Cir. 2018). The purpose and effect of defendants' new blacklisting policies, however, is to refuse to spend duly appropriated funds. These new policies also work to retroactively alter the terms of federal programs. For these reasons, the challenged policies violate the Constitution. And federal courts have well-established equitable powers to enjoin federal officials from exceeding the bounds of their constitutional and statutory authority. *See, e.g.*, *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326-27 (2015).

8. In implementing and enforcing the challenged policies, defendants have caused—and, left unchecked, will continue to cause—direct, immediate, significant, and irreparable harm to plaintiffs and their public research institutions. Plaintiffs are collectively awaiting NIH's decisions on billions of dollars in requested research funding, including millions of dollars in funding for projects that received top marks from the relevant NIH study section. Despite securing a "fundable" score, these applications remain in suspended animation—neither approved nor denied—making it impossible for plaintiffs to plan for the future. And now, NIH's enforcement of the blacklisting policies has led to the termination of millions of dollars (and counting) in grants already issued to plaintiffs' public institutions. The result of these disruptions has been, in a word, devastating. In Massachusetts, for example, the growing uncertainty has forced the Commonwealth's flagship public research institution, the University of Massachusetts, to rescind several dozen offers from prospective biomedical-sciences graduate students for the upcoming academic year, decimating its graduate student program and jeopardizing important lines of research and risking adverse generational impacts on public health research and innovation.

9. For all these reasons, plaintiffs seek swift relief from this Court. The Court should set aside NIH's unlawful blacklisting policies—and the actions taken to implement those policies—and compel the review of applications that the agency has unlawfully withheld.

JURISDICTION AND VENUE

10. This action arises under U.S. Constitution; the APA, 5 U.S.C. §701 *et seq.*; the Public Health Service Act (PHSA), 42 U.S.C. §201 *et seq.*; and federal regulations governing NIH grants. This Court has jurisdiction under 28 U.S.C. §1331.

11. Venue is proper in this district under 28 U.S.C. §1391(e)(1). Defendants are federal agencies and officers sued in their official capacities. The Commonwealth of Massachusetts is a

resident of this judicial district and a substantial part of the events or omissions giving rise to this Complaint occurred within this district.

PARTIES

I. Plaintiffs

12. The Commonwealth of Massachusetts is a sovereign state of the United States of America. Massachusetts is represented by Attorney General Andrea Joy Campbell, the Commonwealth's chief legal officer.

13. The State of California is a sovereign state of the United States of America. California is represented by Attorney General Rob Bonta, the State's chief legal officer.

14. The State of Maryland is a sovereign state of the United States of America. Maryland is represented by and through its chief legal officer, Attorney General Anthony G. Brown.

15. The State of Washington is a sovereign state of the United States of America. Washington is represented by Attorney General Nicholas W. Brown, the State's chief legal officer.

16. The State of Arizona is a sovereign state of the United States of America. Arizona is represented by Attorney General Kristin K. Mayes, the State's chief law enforcement officer.

17. The State of Colorado is a sovereign state of the United States of America. Colorado is represented by and through its Attorney General Phil Weiser. The Attorney General acts as the chief legal representative of the State and is authorized by Colo. Rev. Stat. §24-31-101 to pursue this action.

18. The State of Delaware is a sovereign state in the United States of America. Delaware is represented by Attorney General Kathy Jennings, who is the State's chief law enforcement officer.

19. The State of Hawai‘i is a sovereign state of the United States of America. Hawai‘i is represented by Attorney General Anne Lopez, who is the State’s chief law enforcement officer.

20. The State of Minnesota is a sovereign state of the United States of America. Minnesota is represented by Attorney General Keith Ellison, the State’s chief legal officer.

21. The State of Nevada, represented by and through Attorney General Aaron D. Ford, is a sovereign State within the United States of America. The Attorney General is the chief law enforcement of the State and is authorized to pursue this action under Nev. Rev. Stat. §228.110 and Nev. Rev. Stat. §228.170.

22. The State of New Jersey is a sovereign state in the United States of America. New Jersey is represented by Attorney General Matthew Platkin, who is the State’s chief law enforcement officer.

23. The State of New Mexico is a sovereign state of the United States of America. New Mexico is represented by Attorney General Raúl Torrez, the State’s chief law enforcement officer.

24. The State of New York is a sovereign state of the United States of America. As a body politic and a sovereign entity, it brings this action on behalf of itself and as trustee, guardian, and representative of all residents, and political subdivisions of New York. Attorney General Letitia James is the chief law enforcement officer for New York.

25. The State of Oregon is a sovereign state in the United States of America. Oregon is represented by Attorney General Dan Rayfield, who is the State’s chief legal officer. Attorney General Rayfield is authorized by statute to file suit in federal court on behalf of the State of Oregon to protect the interests of the State. Or. Rev. Stat. §180.060.

26. The State of Rhode Island is a sovereign state of the United States of America. Rhode Island is represented by Attorney General Peter F. Neronha, the State’s chief legal officer.

27. The State of Wisconsin is a sovereign state in the United States of America. Wisconsin is represented by Josh Kaul, the Attorney General of Wisconsin, who is the chief law enforcement officer of Wisconsin and is authorized to sue on behalf of the State, including its public universities.

II. Defendants

28. Robert F. Kennedy, Jr., is the Secretary of Health and Human Services. He is sued in his official capacity.

29. The United States Department of Human and Health Services (HHS) is a federal cabinet department.

30. Jayanta Bhattacharya is the Director of NIH. He is sued in his official capacity.

31. NIH is a federal agency organized under the PHSA, *see* 42 U.S.C. §§203, 281; it is housed within HHS.

32. The following institutes and centers are federal agencies established under the PHSA, *see* 42 U.S.C. §281, and housed within NIH: the National Cancer Institute; the National Eye Institute; the National Heart, Lung, and Blood Institute; the National Human Genome Research Institute; the National Institute on Aging; the National Institute on Alcohol Abuse and Alcoholism; the National Institute of Allergy and Infectious Diseases; the National Institute of Arthritis and Musculoskeletal and Skin Diseases; the National Institute of Biomedical Imaging and Bioengineering; the Eunice Kennedy Shriver National Institute of Child Health and Human Development; the National Institute on Deafness and Other Communication Disorders; the National Institute of Dental and Craniofacial Research; the National Institute of Diabetes and Digestive and Kidney Diseases; the National Institute on Drug Abuse; the National Institute of Environmental Health Sciences; the National Institute of General Medical Sciences; the National Institute of Mental Health; the National Institute on Minority Health and Health Disparities; the

National Institute of Neurological Disorders and Stroke; the National Institute of Nursing Research; the National Library of Medicine; the National Center for Advancing Translational Sciences; the John E. Fogarty International Center for Advanced Study in the Health Sciences; the National Center for Complementary and Integrative Health; and the Center for Scientific Review.

FACTUAL AND LEGAL BACKGROUND

III. Congressional Authorization and Appropriation for NIH Research

A. Creation and Structure of NIH

33. NIH traces its origins to the 1887 establishment of the Hygienic Laboratory, a component of the Marine Hospital Service dedicated to the study of epidemic diseases. Subsequent statutes have transformed that single laboratory into the multifaceted agency at the center of this suit. In 1902, the laboratory assumed responsibility for testing and regulating vaccines and biologic products with the passage of the Biologics Control Act, ch. 1378, 32 Stat. 728. In 1930, Congress redesignated the laboratory as the National Institute (singular) of Health and established fellowships for biological and medical research. *See* Ransdell Act, ch. 251, 46 Stat. 379. In 1937, Congress created the National Cancer Institute, authorizing the new institute to award research grants to nonfederal scientists and to fund fellowships for young researchers. *See* National Cancer Institute Act, ch. 565, 50 Stat. 559. In 1944, Congress made the National Cancer Institute a division of NIH and expanded NIH's support for biomedical research. PHSA, ch. 373, 58 Stat. 682. And in 1948, following the creation of several additional subsidiary institutes, Congress gave the umbrella agency its current name: the National Institutes (plural) of Health. *See* National Heart Act, ch. 481, 62 Stat. 464.

34. Today, NIH is made up of 27 institutes and centers—or "ICs," in NIH parlance—that each specialize in discrete diseases or body systems or carry out distinct projects. According to the agency, "NIH's mission is to seek fundamental knowledge about the nature and behavior of

living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."[8]

35. NIH carries out its mission through both "intramural" research (that is, research conducted in-house at NIH) and "extramural" research (that is, research conducted at outside institutions with NIH financial support). Twenty-five of the agency's institutes and centers—all named as defendants in paragraph 32 above—are involved in issuing or reviewing applications for extramural funding opportunities.[9]

36. NIH is the primary source of federal funding for biomedical and public health research in the United States. In fiscal year 2024, NIH spent over $36 billion on over 60,000 research grants, awarded to recipients in each of the fifty States and the District of Columbia.[10]

37. In addition to supporting numerous scientific breakthroughs (*see supra*, paragraph 2), NIH funds are also critical to the education and training of the next generation of scientists and researchers. NIH's financial awards support postdoctoral fellows, graduate students, and early-career investigators whose work advances scientific discovery and innovation. These funds not only provide financial support, but also enable mentorship, access to cutting-edge resources, and participation in collaborative research environments that are essential for developing the skills, experience, and professional networks needed to sustain the biomedical research enterprise.

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[8] *Mission and Goals*, NIH (Oct. 24, 2024), https://www.nih.gov/about-nih/what-we-do/mission-goals.

[9] The remaining two are the NIH Clinical Center (a research hospital) and the NIH Center for Information Technology (an administrative component responsible for computing and information technology).

[10] *See* United for Medical Research, *NIH's Role in Sustaining the U.S. Economy*, United for Medical Research, at 5 (Mar. 2025), https://bit.ly/3Xz6Wry (tabulating NIH research grants awarded, FY2024); *see also NIH Awards by Location & Organization*, NIH, https://report.nih.gov/award/index.cfm (searchable results); *Research Project Grants*, NIH, https://report.nih.gov/nihdatabook/category/4 (Jan. 2024) (identifying historical data through 2023, and reporting more than 40,000 competitive grant awards in 2022 and 2023).

B. Congressional Authorization for NIH Research

38. NIH's extramural research activities stem from statutory directives: Congress has enacted laws authorizing NIH and its constituent institutes and centers to conduct research and award grants, and it has supplied funding for those activities through regular appropriations.

39. Section 301 of the PHSA, 42 U.S.C. §241, contains Congress's overarching authorization for NIH (as a component of the "Public Health Service") to conduct research and award grants. Subsection (a) of that paragraph states:

> The Secretary [of Health and Human Services] shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams.

And subsection (a)(1) states that:

> The Secretary may make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research.

40. Section 405 of the PHSA, 42 U.S.C. §284, imposes similar responsibilities and confers similar authority on the directors of NIH's institutes and centers. Among other things, each director "shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences," *id.* §284(b)(1)(A), and, to that end, "may make grants and cooperative agreements . . . for research, training, or demonstrations," *id.* §284(b)(2)(A). *See also* 42 U.S.C. §282 (similar, for the NIH director).

C. Congressional Authorization for Specific Programs and Priorities

41. Other sections of the PHSA provide more specific directives to each of NIH's constituent institutes and centers, detailing the ICs' general purposes and establishing initiatives and programs within each of them. *Cf.* 42 U.S.C. §284(b)(1) (providing that, in carrying out the purposes of section 301 of the PHSA, the Secretary, acting through the Director of each research institute within NIH, "shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences" with respect to the human disease or disorder or other aspects of human health for which the national research institutes were established). Some of these statutory provisions are directly at odds with the "agency priorities" articulated in defendants' new blacklisting policies.

42. To take just one example, as described in greater detail below (*see infra*, paragraphs 94-117), defendants have adopted a policy blacklisting research projects with a perceived connection to "DEI." This newly stated policy against diversity, equity, and inclusion is inconsistent with at least the following express statutory directives:

- Congress has provided that the NIH director "shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." 42 U.S.C. §282(h).

- Congress has provided that the NIH director shall "encourage efforts to improve research related to the health of sexual and gender minority populations, including by (1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of Health, and reporting on such participation, as applicable; (2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and (3) addressing methodological challenges." *Id.* §283p.

- Congress has directed various NIH institutes and centers to conduct research related to women's health or reproductive health. For example, it has instructed the National Cancer Institute to "expand, intensify, and coordinate the activities of the Institute with respect to research on breast . . . cancers of the reproductive system of women." *Id.* §285a-6. And it has required the National Heart, Lung, and Blood Institute to conduct research into the

prevalence of certain heart conditions in women, "including African-American women and other women who are members of racial or ethnic minority groups." *Id.* §285b-7a(c)(1)

- Congress has established a National Institute on Minority Health and Health Disparities to support research and training "with respect to minority health conditions and other populations with health disparities." *Id.* §285t(a).[11]

- Congress has established an Office of Research on Women's Health within NIH to "determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation." *Id.* §287d(e).

- Congress has instructed the Secretary of Health and Human Services to award Ruth L. Kirschstein National Research Service Awards "in a manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities), into fields of biomedical or behavioral research and in the provision of research training to women and such individuals." *Id.* §288(a)(4).

D. Congressional Directives Regarding NIH Priority-Setting

43. In addition to the above directives, Congress has also established a public process to identify the research priorities of NIH and its institutes and centers. Every six years, the NIH director must "develop and submit to the appropriate committees of Congress and post on the [NIH's website] a coordinated strategy (to be known as the 'National Institutes of Health Strategic Plan') to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine." 42 U.S.C. §282(m)(1). Each of NIH's institutes and centers similarly develops and promulgates a strategic plan that publicly articulates its research priorities. *Id.* §282(m)(3).

[11] The statutory term "minority health conditions" is defined to mean conditions that are unique to, or more prevalent among, or treated differently in, or understudied with respect to "individuals who are members of" "racial and ethnic minority group[s]"—*i.e.*, "American Indians (including Alaska Natives, Eskimos, and Aleuts); Asian Americans; Native Hawaiians and other Pacific Islanders; Blacks; and Hispanics." 42 U.S.C. §§285t(c)(2)-(3), 300u-6(g)(1).

44. NIH has previously followed Congress's direction and publicized its research priorities. In September 2019, the NIH director began the process of updating the agency's priorities in biomedical and behavioral research areas, research capacity, and research conduct. Between October 2019 and July 2020, NIH gathered feedback from its institutes and centers, their advisory councils, external stakeholders, and the general public. The final Strategic Plan, published in 2021, stated that, among other things, NIH would prioritize "improving minority health and reducing health disparities; enhancing women's health; addressing public health challenges across the lifespan; promoting collaborative science; and leveraging data science for biomedical discovery."[12] Similarly, the plan stated that NIH "supports a comprehensive spectrum of immunology and infectious disease research focused on developing improved or novel vaccines, including the rapid development of new vaccines to mitigate emerging infectious disease outbreaks, such as COVID-19, Ebola virus disease (EVD), and influenza (flu)."[13]

E. Congressional Appropriations for NIH Extramural Research

45. Most of NIH's funding comes from annual discretionary appropriations from Congress.[14] For years, Congress has made appropriations for NIH research with this statutory and regulatory framework in mind and generally has appropriated specific amounts to each of NIH's institutes and centers to carry out the purposes set forth in the authorizing statutory provisions described above.[15]

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[12] NIH, *NIH-Wide Strategic Plan, Fiscal Years 2021-2025* at 3 (2021), https://bit.ly/NIHSP2125.

[13] *Id.* at 8.

[14] Some of NIH's funding is from mandatory funding sources or available due to specific transfer or budgetary rules, but the "vast majority" comes from annual discretionary appropriations. *National Institutes of Health Funding: FY1996-FY2025*, Cong. Research Serv. Rep. (June 25, 2024), https://www.congress.gov/crs-product/R43341.

[15] *See, e.g.*, Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. H, tit. II, 136 Stat. 4459, 4861-65; Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. H, tit. II, 136 Stat. 49, 448-52; Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, div. H, tit. II, 134 Stat. 1182, 1573-77; Further Consolidated

46. In recent years, Congress has specifically rejected efforts to significantly cut NIH's funding. For example, in 2017, as part of its fiscal year 2018 budget proposal, the first Trump Administration sought to reduce NIH annualized spending by $5.8 billion, to $25.9 billion.[16] The proposal's primary method of achieving these cuts was by slashing the "indirect cost rate" for NIH grants, capping it at 10% across the board. This proposal drew bipartisan criticism. The Senate Appropriations Committee reported that the proposal would "radically change the nature of the Federal Government's relationship with the research community," would "abandon[]" the Government's "long-established responsibility" for research infrastructure, and would jeopardize "biomedical research nationwide." S. Rep. No. 115-150, at 109 (2017). To avoid this possibility, Congress enacted statutory language (which it has readopted in every subsequent appropriations measure) barring NIH or any other agency from restructuring or modifying the existing approach to indirect costs. *See* Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, div. H, §226, 132 Stat. 348, 740. And ultimately, rather than enacting the Administration's proposal of cutting NIH funding to $25.9 billion, Congress's all-in appropriation to NIH for fiscal year 2018 was $37.3 billion—higher than the prior fiscal year's appropriation.[17]

47. In subsequent budget proposals, the Administration generally sought to increase, not decrease, NIH's funding. Its Fiscal Year 2020 budget proposal touted the Administration's prioritization of "critical health research" and proposed a $33 billion appropriation to NIH—about

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Appropriations Act, 2020, Pub. L. No. 116-94, div. A, tit. II, 133 Stat. 2534, 2562-65; Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, div. B, tit. II, 132 Stat. 2981, 3074-77; Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, div. H, tit. II, 132 Stat. 348, 720-23; Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, div. H, tit. II, 121 Stat. 135, 524-26; *see also, e.g.*, Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, div. G, tit. II, 121 Stat. 1844, 2173-77.

[16] *See* Off. of Mgmt. & Budget, *Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018*, at 43 (2017), https://bit.ly/OMBFY18.

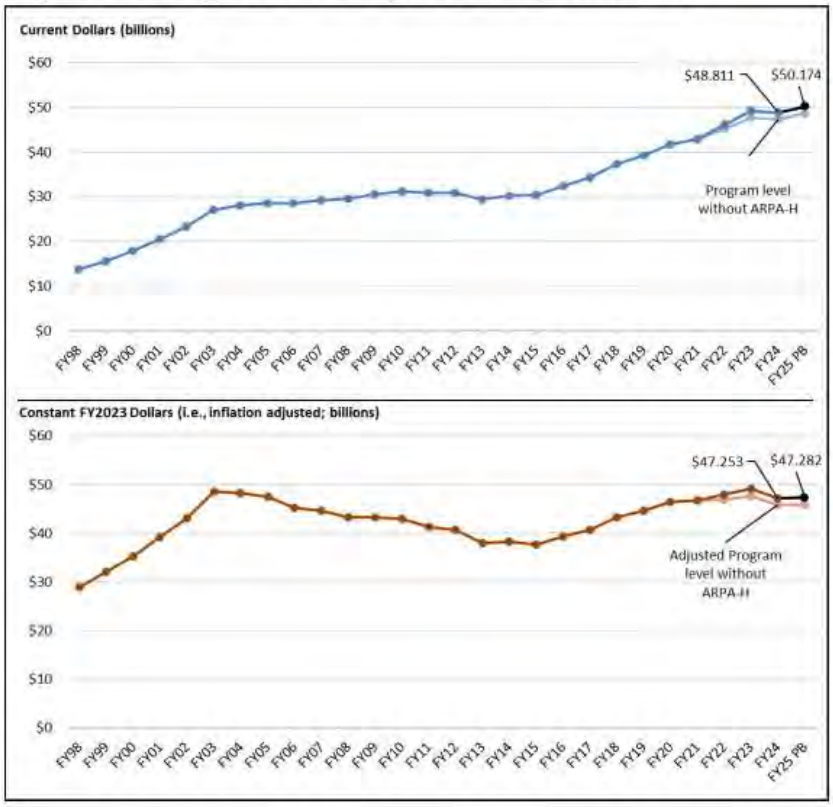
[17] NIH, *History of Congressional Appropriations, Fiscal Years 2010-2019*, at 1, https://bit.ly/42p9Lya.

$6 billion higher than its 2017 proposal.[18] Similarly, the Fiscal Year 2021 budget reiterated the Administration's commitment to prioritizing "critical health research" and "support[ing] innovation," and proposed providing $38 billion to NIH.[19] Ultimately, Congress appropriated even more funds to NIH than the Administration requested for fiscal year 2021: about $42.9 billion.[20]

48. Overall, from Fiscal Years 2017 through 2023, NIH funding increased annually, which is consistent with NIH's stable, and generally increasing, funding for more than 20 years:[21]

Figure 1. NIH Funding, FY1998-FY2025 Request

Program Level Funding in Current and Projected Constant (FY2023) Dollars.



[18] Off. of Mgmt. & Budget, *Budget of the U.S. Gov't, Fiscal Year 2020*, at 46, https://bit.ly/OMBFY20.

[19] Off. of Mgmt. & Budget, *A Budget for America's Future, Fiscal Year 2021*, at 54, bit.ly/OMBFY2021.

[20] NIH, *Supplementary Appropriation Data Table for History of Congressional Appropriations, Fiscal Years 2020-2025*, at 1, bit.ly/42dM1M4.

[21] *National Institutes of Health Funding: FY1996-FY2025*, Cong. Research Serv. Rep. (June 25, 2024), https://www.congress.gov/crs-product/R43341.

49. Congress's appropriations to NIH for Fiscal Year 2024 were no different. Consistent with past appropriations for NIH activities, the Further Consolidated Appropriations Act of 2024 (2024 CAA) appropriates to each of NIH's Institutes and Centers specific amounts "for carrying out section 301 and title IV of the [Public Health Service] Act" with respect to their specific, respective statutory purposes. Pub. L. 118-47, div. D, tit. II, 138 Stat. 460, 656-57. For example, the 2024 CAA appropriates $7,224,159,000 to the National Cancer Institute "for carrying out section 301 and title IV of the [PHSA] with respect to cancer"; $3,982,345,000 to the National Heart, Lung, and Blood Institute to carry out the same statutory purposes "with respect to cardiovascular, lung, and blood diseases, and blood and blood products"; and $2,603,925,000 to the National Institute for Neurological Disorders and Stroke to carry out the same statutory purposes "with respect to neurological disorders and stroke." *Id.*

50. Congress has not enacted a Consolidated Appropriations Act for Fiscal Year 2025, but on March 15, 2025, the President signed the Full-Year Continuing Appropriations and Extensions Act, 2025, commonly known as a "Continuing Resolution" or "CR" (2025 CR). Pub. L. 119-4, 139 Stat. 9. Pursuant to the 2025 CR, Congress appropriated "[s]uch amounts as may be necessary . . . under the authority and conditions provided in applicable appropriations Acts for fiscal year 2024, for projects or activities . . . that are not otherwise specifically provided for, and for which appropriations, funds, or other authority were made available" in the specific appropriations Acts. *Id.*, div. A, §1101(a), 139 Stat. at 11. Congress made limited changes in the 2025 CR with respect to the appropriation to NIH, including rescission of a portion of NIH funding ($221,000,000 of a $1.25 billion appropriation) previously appropriated to the "NIH Innovation Account, CURES Act," which is separate from Congress's discretionary appropriations to NIH's

institutes and centers. *Id.*, div. A, §1905, 139 Stat. at 32.[22] Otherwise, Congress did not rescind any amounts appropriated to NIH's ICs and maintained the same level of funding as set forth in the 2024 CAA, through September 30, 2025. *See id.*, div. A, §1101(a)(8), 139 Stat. at 11.

IV. The Grant Application and Award Process

51. NIH generally awards extramural grants through a competitive process. At any given time, NIH has over a thousand active funding opportunities supporting a broad range of programs.

52. HHS has promulgated regulations at 45 C.F.R. part 75, governing the award of grants by HHS and its agencies, including NIH. This includes 45 C.F.R. §52.6(c), which allows HHS to notice a grant award for a "project period," during which HHS intends to support the project "without requiring the project to recompete for funds."

53. NIH uses three-character "activity codes" to group and classify these funding opportunities, with the first character typically identifying the major funding category or program type. "For example, activity codes for research and development often start with 'R,' training with 'T,' fellowship with 'F,' and career development with 'K.'[23] The "R01" code, for example, denotes grants "[t]o support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his or her specific interest and competencies."

54. The NIH competitive grantmaking process begins with a notice of funding opportunity (NOFO)—*i.e.*, a public announcement in which NIH declares its intention to award

[22] Appropriations to the account created by the Cures Act are, "[i]n effect," "not subject to discretionary spending limits." *Nat'l Insts. of Health Funding: FY1996-FY2025*, Cong. Research Serv. Rep. (June 25, 2024), https://www.congress.gov/crs-product/R43341. Funds may be transferred from the Cures Act account to other NIH accounts "only for the purposes specified in the Cures Act." *Id.* Congress exempted from any rescission amounts previously designated by Congress as for an "emergency requirement" under the Balanced Budget and Emergency Deficit Control Act of 1985. 2025 CR, div. A, §1101(a)(8), 139 Stat. at 11

[23] *Activity Codes*, NIH (March 28, 2025), https://grants.nih.gov/funding/activity-codes; *see Funding Categories*, NIH (Feb. 3, 2025), https://grants.nih.gov/funding/funding-categories.

funds and outlines the program goals and objectives and conditions for applying. *See* NIH Grants Policy Statement, U.S. Dep't of Health & Hum. Servs. §2.3.5, at I-51 (Apr. 2024) (NIHGPS).

55. A researcher interested in responding to a NOFO will typically work with the "sponsored research" department at his or her institution to understand what NIH requires in its application submission. At UMass Medical School, for example, the Office of Sponsored Programs assists faculty and staff in locating sources of funding, reviewing and approving proposals, and negotiating grants and contracts.

56. Once a researcher develops a project proposal, that person then submits an electronic grant application to NIH. Applications must conform to 45 C.F.R. part 75, and must include a detailed research plan outlining the study's objectives, methodology, and significance; a proposed budget and justification; biosketches for key investigators; and any necessary compliance documentation, such as Institutional Review Board approval for human subject research.

57. A submitted grant application undergoes two layers of evaluation: an initial layer of review by a "scientific review group" (also known as a "study section"), followed by a round of review by an "advisory council." *See* 42 U.S.C. §§284a, 289a; *see also* NIHGS §2.4, at I-71 ("The peer review system used by NIH, often referred to as the 'dual review system,' is based on two sequential levels of review for each application—initial review by [a study section], and a second level of review for scientific merit by the IC National Advisory Council/Board."). According to NIH, this process "is intended to ensure that applications for funding submitted to NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias." NIHGS §2.4, at I-71.

58. As noted, the first level of application review is carried out by a study section. The role of study sections is to assess applications' scientific merit and to determine the overall impact

that proposed projects will likely have on the relevant field. Governing statutes and regulations require this layer of review—*i.e.*, a favorable study-section recommendation is a prerequisite to a final award of any NIH grant. *See* 42 U.S.C. §§ 284(b)(2)(B), 289a(a); 42 C.F.R. pt. 52h.

59. These groups consist primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. 42 C.F.R. §52h.4. NIH has hundreds of study sections, organized by specialty. In the field of Kidney, Urology, and Digestive Systems, for example, NIH maintains study sections on (a) Drug and Biologic Disposition and Toxicity; (b) Digestive System Host Defense, Microbial Interactions, and Immune and Inflammatory Diseases; (c) Digestive and Nutrient Physiology and Diseases; (d) Environmental Determinants of Disease (e) Hepatobiliary Pathophysiology; (f) Kidney and Urological Systems Function and Dysfunction; and Pathobiology of Kidney Disease, as well as two "special emphasis panels" on Digestive Sciences Small Business Activities and Renal and Urological Sciences Small Business Activities. Some study sections are housed in NIH's individual institutions and centers, while others are organized centrally in the agency's Center for Scientific Review.

60. Study sections carry out their work—including review of pending applications—at regularly scheduled meetings. These meetings must be noticed in advance in the Federal Register. *See* 42 C.F.R. §52h.3 ("To the extent applicable, the Federal Advisory Committee Act, as amended . . . shall govern the establishment and operation of peer review groups."); 5 U.S.C. §1009(a)(2) ("[T]imely notice of each meeting [subject to the Federal Advisory Committee Act] shall be published in the Federal Register . . . .").

61. Study sections review and score each grant application according to established criteria set forth in regulations and the NOFO. In particular, the study section assesses the overall impact that the project could have on the research field involved, taking into account:

(a) The significance of the goals of the proposed research, from a scientific or technical standpoint;

(b) The adequacy of the approach and methodology proposed to carry out the research;

(c) The innovativeness and originality of the proposed research;

(d) The qualifications and experience of the principal investigator and proposed staff;

(e) The scientific environment and reasonable availability of resources necessary to the research;

(f) The adequacy of plans to include both genders, minorities, children and special populations as appropriate for the scientific goals of the research;

(g) The reasonableness of the proposed budget and duration in relation to the proposed research; and

(h) The adequacy of the proposed protection for humans, animals, and the environment, to the extent they may be adversely affected by the project proposed in the application.

42 C.F.R. §52h.8; *see also* 42 C.F.R. §52a.5 (describing review criteria for NIH research center grants); 42 C.F.R. §52h.11 (describing review criteria for NIH research contracts).

62. As a result of that review, each grant application receives an "overall impact score" from 10 (the best score, denoting high impact) to 90 (the worst score, denoting low impact). Each application also receives a percentile rank expressing the impact score in relation to other applications in that particular institute. Projects deemed "unfundable" by the study section are not given a score and are removed from further consideration.

63. Each fiscal year, NIH's institutes and centers publish guidance called "paylines" to help applicants interpret their study-section results. These paylines reflect a sort of cutoff: for each category of grants, the payline shows the impact score (or percentile) above which a project is highly likely to be funded. In Fiscal Year 2025, for example, published guidance from the National Institute of Allergy and Infectious Diseases (NIAID) established a 12th-percentile payline for

"R01" awards with new or early-stage principal investigators.[24] In other words, an applicant in that category who received a score from the relevant study section within the 12th percentile could anticipate that NIAID would likely fund his or her project. Study-section scores that meet or exceed the payline in this way are commonly referred to as "fundable" scores.

64. In addition to providing scores and percentiles, study sections also provide each applicant with a "summary statement" that contains, among other things, a brief summary of the study section's discussion, bulleted critiques from assigned reviewers, and any administrative comments. Applicants can use these summary statements to revise applications and address concerns, if necessary.

65. As noted, the second level of application review is carried out by an advisory council. Unlike the numerous study sections, each NIH institute or center that funds grants has a single advisory council (*i.e.*, there is one advisory council for NIAID, one for the National Cancer Institute, and so on). By statute, NIH advisory councils must meet at least three times per fiscal year. 42 U.S.C. §284a(3). Like study section meetings, advisory council meetings must be noticed in advance in the Federal Register. *See* 41 C.F.R. §102-3.150 (requiring 15 days' notice).

66. Whereas a study section's review focuses on scientific merit, an advisory council's review weighs programmatic and institute-wide considerations. A council considers, among other things, the extent to which an application aligns with the institute or center's priorities, public health needs, and overall funding availability. The council also reviews the application for other potential barriers, such as ethical issues around human or animal test subjects.

67. An advisory council makes one of three decisions on each application: an application is recommended for funding, not recommended for funding, or deferred for re-review

[24] *NIAID Paylines*, NIAID (Dec. 17, 2024), https://www.niaid.nih.gov/grants-contracts/niaid-paylines.

by the study section. A favorable recommendation from the relevant institute's advisory council is a prerequisite to final award of any grant in excess of $50,000. 42 U.S.C. § 284(b)(2); *see also* §284a(a)(3)(A)(ii).

68. The advisory council makes funding recommendations to the institute or center director, who ultimately makes the funding decision. In making that decision, the institute or center director shall consider, consistent with the peer-review process: (i) the mission of the national research institute or national center and the scientific priorities identified in the institute or center's strategic plan; (ii) programs or projects funded by other agencies on similar research topics; and (iii) advice by staff and the advisory council or board of such national research institute or national center. 42 U.S.C. §284(b)(3).

69. If the decision is in favor of funding, NIH issues a legally binding Notice of Award (NOA) to the selected grant recipients stating that funds may be requested. NIHGMS §5, at IIA-59.

70. NIH typically does not issue grants as lump-sum awards. Instead, NIH uses a cost-based accounting system, under which grant recipients are authorized to recover their actual, documented costs for conducting research after the grant is awarded. Institutions can then use awards—and indeed, rely on those awards—to obtain a line or letter of credit for the procurement of the resources needed for the project.

71. If NIH approves a project with a multi-year period, the agency typically awards the grant for the first year (the "award year") at the outset, with funding for subsequent years (the "out years") subject to a renewal process. In these "non-competing" renewals, the application does not undergo a fresh round of peer review—instead, applicants submit progress reports demonstrating that the grantee is making progress and complying with applicable policies and practices. *See* 42

C.F.R. §52a.6. So long as grantees demonstrate progress and compliance with applicable policies and practices, non-competing renewals are approved as a matter of course.

72. NIH's application and award process follows a predictable calendar each year that is posted in advance. The agency has three standard application cycles per year, with published schedules identifying application due dates, the timing of study section and advisory council review, and the earliest permissible start date for the project. As reflected on the agency's website,[25] the current triannual schedule is as follows:

Review and Award Cycles

	Cycle I	Cycle II	Cycle III
Application Due Dates	January 25 - May 7	May 25 - September 7	September 25 - January 7
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

73. According to Michelle Bulls, NIH's Chief Grants Management Officer, before 2025, NIH typically only terminated grants either with the consent of the award recipient or where the recipient failed to comply with the terms and conditions of the award and NIH was unable to identify corrective action. Mutual terminations can occur when the principal researcher associated with a grant can no longer undertake research. According to Ms. Bulls, since 2012, NIH has terminated less than five grants for non-compliance with the terms and conditions of the original grant award.

[25] *Standard Due Dates*, NIH (Aug. 23, 2024), https://grants.nih.gov/grants-process/submit/submission-policies/standard-due-dates.

V. Plaintiffs' Receipt of NIH Grants

74. Plaintiffs' state universities and colleges, as well as other research institutions, depend heavily on NIH funding to support biomedical and public health research. At any given time, individual research universities may depend on thousands of NIH grants that support independent research projects across multiple university facilities.

75. Plaintiff Massachusetts operates the University of Massachusetts (UMass), the Commonwealth's flagship public research institution, which consists of the UMass Amherst, UMass Boston, UMass Dartmouth, UMass Lowell, and the UMass Chan Medical School. *See generally* Mass. G.L. c. 75, §1. In Fiscal Year 2024, UMass campuses collectively received $248 million in NIH funding, supporting at least 501 projects.

76. The University of California (UC) is a corporation established under article IX, §9, of the California Constitution and located within the State of California; it is an exempt state government entity. The UC system consists of 10 research-intensive campuses, 21 health professional sciences schools, 5 NCI-designated cancer centers, and 6 academic medical centers. The UC system's constituent schools and institutions are widely recognized as among the best in the nation, serving as international leaders in the education of health professionals, the development of new cures and treatments, and the provision of healthcare for all Californians regardless of ability to pay. The University of California is one of the nation's leading research institutions, with almost 9% of all U.S. academic research being conducted by UC researchers. Biomedical advancements at UC include the first radiation treatment for cancer, research contributing to the first flu vaccine, the discovery of the role of LDL and HDL cholesterol in heart disease, the invention of modern gene editing, and much more. Every year, UC system researchers submit thousands of NIH grant applications, and the world-leading researchers on UC's faculty serve on numerous NIH study sections and advisory councils to assess grant applications for

scientific and technical merit. NIH contracts and grant funding support many of the clinical trial studies at UC's six medical centers.

77. Federal funds are UC's single most important source of support for its research, accounting for more than half of UC's total research awards. In Fiscal Year 2024, UC received a total of over $2 billion in NIH contract and grant funding to support more than 5000 research projects. The estimated value of just the NIH grant proposals submitted by the five UC Health Centers as of December 31, 2024, that have not yet been acted upon is approximately $563 million. Grant proposals awaiting study sections before July 1, 2025, have an annual value of approximately $312 million, while grants awaiting advisory councils and Notices of Awards have an annual value of approximately $251 million. The UC Health Center in San Francisco (UCSF) alone is has 1,650 unique principal investigators with 4,110 active NIH awards.

78. Plaintiff California also operates the California State Universities (CSU), the largest four-year public university system in the United States. The purpose of the CSU system as established by statute is to provide access to education and the opportunity for educational success for all qualified Californians. Cal. Educ. Code §66010.2. CSU consists of 23 campuses, nearly a dozen off-campus centers, and over 90 auxiliary organizations (several dedicated to sponsored research). During Fiscal Year 2024, the CSU expended nearly $90 million in NIH contract and grant funding to support approximately 250 projects across 18 universities with the total multi-year award funding in the hundreds of millions.

79. Plaintiff Maryland operates the University System of Maryland (USM), a system of 12 constituent institutions, including leading research institutions at the University of Maryland, Baltimore (UMB), and the University of Maryland, College Park (UMCP). In fiscal year 2024, UMB received $213.9 million in active NIH awards and an additional $34.2 million in NIH pass-

through funding; UMCP received $68 million in funding awarded directly by the NIH and $9 million in funding awarded on a pass-through basis from the NIH.

80. Plaintiff Washington operates the University of Washington, the largest recipient of federal research funding of any public university in the country. In Fiscal Year 2024, University of Washington received over $648 million in NIH funding, supporting over 1,220 projects.

81. Arizona State University, Northern Arizona University, and the University of Arizona are instrumentalities of the State of Arizona. In Fiscal Year 2024, those universities together managed approximately 426 NIH awards totaling over $286 million.

82. Colorado established the University of Colorado Anschutz Medical Campus (CU Anschutz) as the only academic medical research campus in Colorado. *See generally* Colo. Rev. Stat. §23-21-101, *et. seq.* In Fiscal Year 2024, CU Anschutz received $360 million in NIH funding, which represented 48% of all sponsored awards for the year.

83. Plaintiff Delaware's flagship research institution, The University of Delaware, received $66 million in NIH funding, supporting 135 projects in Fiscal Year 2024.

84. Plaintiff Hawai'i operates the University of Hawai'i, which houses some 3,000 researchers and enrolls around 30,000 students across 10 campuses. The University of Hawai'i includes the John A. Burns School of Medicine, the University of Hawai'i Cancer Center, the Daniel K. Inouye School of Pharmacy, the School of Nursing and Dental Hygiene, the Thompson School of Social Work, and several other schools that conduct fundamental, translational, clinical and community-based participatory research in health sciences and health care. In Fiscal Year 2024, the University of Hawai'i received more than $65 million in direct NIH funding, supporting 75 projects.

85. With respect to Plaintiff State of Minnesota, NIH has awarded tens of millions of dollars to the University of Minnesota. For example, in Fiscal Year 2024 alone, the University of Minnesota received 808 awards directly from NIH which obligated funding to the University of approximately $355.6 million.

86. Nevada operates the Nevada System of Higher Education, which includes the University of Nevada, Las Vegas, and the University of Nevada, Reno. In Fiscal Year 2024, the University of Nevada, Las Vegas received $11.9 million and the University of Nevada, Reno received $9.5 million dollars in NIH funding.

87. With respect to Plaintiff New Jersey, three major State research institutions—Rutgers, the State University of New Jersey (Rutgers), New Jersey Institute of Technology (NJIT), and Kean University (Kean)—have a significant academic and clinical health sciences presence across the State, including numerous research centers and institutes, academic medical centers, and colleges of liberal arts and sciences, schools of environmental and biological sciences, engineering, and other professional schools and graduate programs. In Fiscal Year 2024, these three institutions and their affiliated campuses collectively received approximately $250 million in NIH funding to support approximately 1,200 projects, including grants that support undergraduate students from under-represented populations pursuing biomedical sciences and engineering degrees and graduate programs.

88. Plaintiff New Mexico operates the University of New Mexico (UNM), which is the state's flagship research university with research centers spanning the fundamental sciences, technology and engineering research, education, humanities and social sciences, and human health. UNM is the only academic health system in the state; it pursues research on improving human health, including substance use disorders, cardiovascular and metabolic disease, infectious

diseases and immunity, Alzheimer's disease, kidney disease, cancer, and pediatrics, and more. This research was supported by $107 million from the NIH in Fiscal Year 2024 and, through early February 2025, estimated NIH funding for Fiscal Year 2025 is over $126 million. Plaintiff New Mexico also operates New Mexico State University (NMSU), a university with over sixty research facilities focusing on fundamental sciences, physical sciences, agriculture, the arts, humanities and social sciences, economics, engineering, and human health. This research was supported by over $10 million from the NIH in Fiscal Year 2024 and, through early February 2025, estimated NIH funding for Fiscal Year 2025 is over $30 million.

89. New York operates the State University of New York (SUNY), which is comprised of 64 colleges and universities, of which four campuses are designated R1 research institutions. In fiscal year 2024, SUNY received $237.5 million from NIH to support 894 projects.

90. The Oregon Health and Science University (OHSU) is a public corporation of the State of Oregon and is Oregon's only public academic health center. OHSU is not the only public recipient of NIH funding in Oregon, but it receives the largest amount of NIH funding. In fiscal year 2024, OHSU received over $350 million in NIH funding to support 784 projects and over 1,400 researchers. The University of Oregon, Oregon State University, and Portland State University are also public recipients of NIH funding.

91. The University of Rhode Island (URI) is Rhode Island's flagship public university. *See* 16 R.I. Gen. Laws Ann. §16-32-3. In fiscal year 2024, URI received $22.1 million in NIH funding to support over 90 projects.

92. Plaintiff Wisconsin operates the Universities of Wisconsin, which includes prominent research institutions at the University of Wisconsin-Madison (UW-Madison) and University of Wisconsin-Milwaukee (UW-Milwaukee). UW-Madison's research enterprise is

particularly robust, encompassing more than $1.7 billion in annual research expenditures. Approximately one third of sponsored research at UW-Madison is awarded by the NIH. In fiscal year 2024, UW-Madison received direct funding from NIH to support 588 projects, totaling more than $404 million. UW-Madison funds 4,942 researchers and staff through direct NIH grants, and its work on NIH-funded projects provides scientific education and research training in medical and health sciences, biology, public health, biochemistry, psychology, and other disciplines. In fiscal year 2024, UW-Milwaukee also received funding from NIH to support dozens of projects, totaling $7.9 million.

CHALLENGED AGENCY ACTIONS

93. This lawsuit arises because defendants are flouting the statutory and regulatory rules governing NIH grantmaking. As explained below, defendants have adopted a series of directives that blacklist certain topics—*e.g.*, "DEI," "gender," or "vaccine hesitancy"—that the Administration disfavors. In adopting, implementing, and enforcing those directives, defendants have systematically disrupted the review of pending grant applications, delayed the annual renewal of already-approved multi-year awards, and terminated huge tranches of grants in the middle of the project year. Those disruptions have caused—and will continue to cause—significant harm to plaintiffs and their institutions.

I. The Administration's Adoption of Executive Orders and OMB Directives Identifying Politically Disfavored Topics

94. The NIH-specific directives that plaintiffs challenge here (*see infra*, paragraphs 102-117) in large part implement a series of executive orders and Administration directives issued on or shortly after Inauguration Day.

95. On January 20, 2025, President Trump signed Executive Order 14151, entitled "Ending Radical Government DEI Programs and Preferencing" (DEI Order). The DEI Order aims

to terminate any federal programs that promote "diversity, equity, and inclusion," "diversity, equity, inclusion, and accessibility," and "environmental justice." The order does not define those terms. The order further directs "[e]ach agency, department, or commission head, in consultation with the Attorney General, the Director of OMB, and the Director of OPM" to "terminate, to the maximum extent allowed by law, . . . all . . . 'equity-related' grants or contracts." DEI Order §2(b)(1). The order does not define "equity-related."

96. The same day, the President signed Executive Order 14168, entitled "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government" (Gender Ideology Order). The order denies the existence of transgender, nonbinary, intersex, or other gender-nonconforming people and rejects "gender ideology," which it vaguely defines as "replac[ing] the biological category of sex with an ever-shifting concept of self-assessed gender identity, permitting the false claim that males can identify as and thus become women and vice versa, and requiring all institutions of society to regard this false claim as true." Gender Ideology Order §§1-2. The order directs all federal agencies to "take all necessary steps, as permitted by law, to" strip federal funds from anyone who promotes "gender ideology," demanding that "[e]ach agency shall assess grant conditions and grantee preferences and ensure grant funds do not promote gender ideology." *Id.* §3(e), (g).

97. The following day, the President signed Executive Order 14173, entitled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity" (Discrimination Order). The order targeted what it called "race- and sex-based preferences under the guise of so-called 'diversity, equity, and inclusion' (DEI) or 'diversity, equity, inclusion, and accessibility' (DEIA),'" but again failed to define those terms. The order requires that "[t]he head of each agency shall include in every contract or grant award . . . [a] term requiring" any federal grant "recipient

to certify that it does not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws." *Id.* §3(b)(iv)(B). It also threatens civil False Claims Act enforcement against any grantee failing to comply with the Discrimination Order's vague and undefined terms. *Id.* §3(b)(iv)(A). Likewise, the Discrimination Order threatens lawsuits against private entities that promote DEI. *Id.* §4(b)(v).

98. On January 27, the acting director of the Office of Management and Budget (OMB) issued OMB Directive M-25-13 (OMB Directive). The OMB Directive targeted a broad swath of federal fund disbursements for a near-immediate freeze. This directive stated that all federal agencies "must complete a comprehensive analysis of all of their Federal financial assistance programs to identify programs, projects, and activities that may be implicated by any of the President's executive orders." While this analysis is ongoing, "[i]n the interim, to the extent permissible under applicable law, Federal agencies **must temporarily pause** all activities related to obligation or disbursement of all Federal financial assistance, and other relevant agency activities that may be implicated by the executive orders, including, but not limited to, financial assistance for foreign aid, nongovernmental organizations, DEI, woke gender ideology, and the green new deal" (emphasis in original). The OMB Directive ordered that the temporary pause take effect the following day, on January 28, 2025, at 5:00 PM.

99. On January 28, the U.S. District Court for the District of Columbia ordered an administrative stay of the OMB Directive pending a hearing on a motion for a temporary restraining order. Order of Administrative Stay (ECF No. 13), *Nat'l Council of Nonprofits, et al. v. Trump, et al.*, No. 1:25-cv-239-LLA (D.D.C. filed Jan. 28, 2025). At approximately 1:00 PM Eastern Time on January 29, OMB issued M-25-14, a memorandum purportedly rescinding the OMB Directive in two sentences: "OMB Memorandum M-25-13 is rescinded. If you have

questions about implementing the President's Executive Orders, please contact your agency General Counsel."

100. Shortly after OMB purported to rescind the OMB Directive, however, White House Press Secretary Karoline Leavitt stated that the federal funding freeze remained in place, notwithstanding the rescission of the OMB Memorandum. Leavitt announced on social media: "This is NOT a rescission of the federal funding freeze. It is simply a rescission of the OMB memo. Why? To end any confusion created by the court's injunction. The President's EO's on federal funding remain in full force and effect and will be rigorously implemented."

101. At a press conference that same day, Leavitt stated: "So, what does this pause mean? It means no more funding for illegal DEI programs. It means no more funding for the Green New Scam that has . . . cost American taxpayers tens of billions of dollars. It means no more funding for transgenderism and wokeness across our federal bureaucracy and agencies. No more funding for Green New Deal social engineering policies."

II. Defendants' Adoption of NIH-Specific Directives Blacklisting Politically Disfavored Topics

102. Defendants have subsequently issued directives to and within NIH that carry out and expand upon the foregoing executive orders and policy objectives. Specifically, defendants formulated, adopted, and executed a series of policies blacklisting entire categories of research that the Administration disfavors for political reasons. These categories originally focused on "DEI-related" projects, but have evolved to include other disfavored categories, including projects related to gender identity, vaccine hesitancy, COVID-19, and climate change.

103. On January 21, Acting Secretary of Health and Human Services Dorothy Fink issued a memorandum to all HHS subcomponents entitled "Immediate Pause on Issuing Documents and Public Communications" (Notice Pause Directive). A copy of the Notice Pause

Directive is attached as Exhibit 1 to this Amended Complaint and is incorporated herein by reference. The Notice Pause Directive instructed, among other things, that no notices be submitted for publication to the Federal Register unless approved by a presidential appointee.

104. On February 10, 2025, Acting Secretary of Health and Human Services Dorothy Fink issued a "Secretarial Directive on DEI-Related Funding" (Secretarial Directive). A copy of the Secretarial Directive is attached as Exhibit 2 to this Amended Complaint and is incorporated herein by reference.

105. The Secretarial Directive stated, in relevant part:

> The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

The Secretarial Directive went on to state:

> For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. §75.371-372, the Secretary of Health and Human Services hereby DIRECTS as follows:
>
> > **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

The Secretarial Directive did not define the term "related to DEI and similar programs."

106. On February 12, Dr. Michael Lauer, then NIH's Deputy Director for Extramural Research, issued a memorandum entitled "NIH Review of Agency Priorities Based on the New Administration's Goals" (Lauer Memorandum). A copy of the Lauer Memorandum is attached as Exhibit 3 to this Amended Complaint and is incorporated herein by reference. The memorandum stated that "NIH is in the process of reevaluating the agency's priorities based on the goals of the new administration," but that, "given recent court orders" in federal court actions related to funding freezes, NIH institutes and centers were "authorized, along with their respective grant management staff, to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements . . . grants."

107. On February 13, Dr. Lauer issued a memorandum entitled "Supplemental Guidance to Memo Entitled- NIH Review of Agency Priorities Based on the New Administration's Goals" (Supplemental Lauer Memorandum). A copy of the Supplemental Lauer Memorandum is attached as Exhibit 4 to this Amended Complaint and is incorporated herein by reference. The memorandum instructed the ICs' Chief Grants Management Officers that "[i]f the sole purpose of the grant . . . supports DEI activities, then the award must be fully restricted." It also called for "hard funding restrictions" where the program promotes initiatives that "discriminate" on the basis of race, sex, or other protected characteristics, without defining what constituted such discrimination in a research program. The Supplemental Lauer Memorandum did not refer to terminations of awards, but rather NIH's funding of programs more generally. That day, Dr. Lauer resigned from his position with NIH.

108. On or about March 4, NIH issued a directive entitled "Award Assessments for Alignment with Agency Priorities—March 2025" (Priorities Directive). A copy of the Priorities Directive—including the several appendices attached to the Priorities Directive— is attached as

Exhibit 5 to this Amended Complaint and is incorporated herein by reference. The Priorities Directive "rescind[ed]" the Supplemental Lauer Memorandum, attached and reaffirmed the Secretarial Directive, and provided further instructions related to "DEI" research.

109. Specifically, the Priorities Directive stated that "NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI)." To enforce that determination, the directive instructed that, "[p]rior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims [to] assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities." The directive further instructed ICs to "completely excise all DEI activities" using a list of predetermined categories, including awards that "ICs must not issue" (Category 1), awards that ICs could issue on certain conditions (Categories 2 and 3), and awards that ICs "may proceed with issuing" (Category 4).

110. The appendices to the Priorities Directive provided NIH staff with specific language "to use when terminating awards identified by HHS or the IC" related to politically disfavored topics. Among other things, NIH staff were instructed to inform grant recipients that "NIH is taking this enforcement action in accordance with 2 C.F.R. §200.340 as implemented in NIH GPS Section 8.5.2." The Priorities Directive's appendices also identified three specific disfavored topics by name: "China," "DEI," and "[t]ransgender issues."

111. The Priorities Directive classified "diversity supplements" as Category 1 awards—*i.e.*, it instructed that "ICs must not issue the award." Diversity Supplements are grants meant to increase diversity in the scientific profession by providing training, mentorship and career development opportunities to individuals from underrepresented populations. For recent notices of funding opportunity, NIH adopted a policy that defined diversity broadly, to include not only

"[i]ndividuals from racial and ethnic groups that have been shown by the [National Science Foundation] to be underrepresented in health-related sciences on a national basis," but also "[i]ndividuals with disabilities," and "[i]ndividuals from disadvantaged backgrounds," including those who have experienced homelessness, who were in foster care, who experienced poverty, or who are from rural areas.[26]

112. By March 13, the list of scientific research disfavored by the Administration had grown to include yet another topic: vaccine hesitancy. Specifically, Michelle Bulls, NIH's Chief Grants Management Officer, issued guidance entitled "Award Revision Guidance and List of Terminated Grants via letter on 3/12" (Award Revision Guidance). A copy of the Award Revision Guidance is attached as Exhibit 6 to this Amended Complaint and is incorporated herein by reference. The Award Revision Guidance again instructed the individual institutes on how to issue termination letters, and on what bases. Ms. Bulls instructed that termination letters should include the following language: "It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated." The termination category language that Ms. Bulls provided included terminations for a program's relation to China, DEI, gender, and vaccine hesitancy. Hundreds of NIH grants were terminated in the ensuing days.[27]

113. Upon information and belief, on or before March 19, the Office of Extramural Research and the Office of Policy for Extramural Research Administration provided additional guidance on how ICs should process grant terminations and communicate with grant recipients regarding such terminations. Included in these instructions was the instruction to speak only of "changes in NIH and/or HHS priorities" and an instruction to "not refer to any Executive Orders."

[26] *PA-20-222: Research Supplements to Promote Diversity in Health-Related Research*, NIH, https://grants.nih.gov/grants/guide/pa-files/pa-20-222.html.

[27] *HHS Grants Terminated*, HHS, https://taggs.hhs.gov/Content/Data/HHS_Grants_Terminated.pdf.

114. On March 25, NIH issued a directive entitled "NIH Grants Management Staff Guidance—Award Assessments for Alignment with Agency Priorities—March 2025" (Revised Priorities Directive). The Revised Priorities Directive and its appendices are attached as Exhibit 7 to this Amended Complaint and are incorporated herein by reference. The Revised Priorities Directive continued to blacklist research related to DEI, transgender issues, and vaccine hesitancy, but now included yet another topic—COVID-19. As to COVID, the guidance stated that: "The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary."

115. Upon information and belief, sometime during mid-March, defendants issued a further directive adding research related to the health effects of climate change as a blacklisted topic (Climate Change Directive).[28]

116. Upon information and belief, on or after January 20, 2025, defendants have issued other directives, including nonpublic and undisclosed directives, that curtail NIH's support for previously advertised funding opportunities and previously awarded grants relating to the blacklisted topics described above.

117. For ease of reference, this Amended Complaint refers to the Secretarial Directive, the Lauer Memorandum, the Supplemental Lauer Memorandum, the Priorities Directive, the Award Revision Guidance, the Revised Priorities Directive, and the Climate Change Directive—as well as other nonpublic and undisclosed directives that curtail NIH's support for previously

[28] Waldman A., *NIH Ends Future Funding to Study the Health Effects of Climate Change*, ProPublica (March 24, 2025), https://www.propublica.org/article/nih-funding-climate-change-public-health.

advertised funding opportunities and previously awarded grants relating to those blacklisted topics—collectively as the "Challenged Directives."

III. Defendants' Implementation of the Challenged Directives Through Elimination of Funding Opportunities and Disruption of Pending Applications

A. Delay and Withholding of Advisory Council and Study Section Meetings

118. Defendants have also been systematically delaying and advisory council and study section meetings in a manner that contravenes prior regulatory notices and NIH's own guidance. As explained above, NIH's own guidance states that "Cycle II" grant applications, which underwent study-section review last fall, were originally scheduled to undergo advisory-council review in January of this year. *See supra*, paragraph 72. And "Cycle III" applications, which researchers submitted to NIH last fall, were scheduled to undergo study-section review in February and March of this year. *See id.* Almost none of that has happened.

119. Although meetings for the advisory councils of 21 different institutes and centers had been scheduled for January and February 2025 via publications in the Federal Register, all but one were abruptly canceled after Inauguration Day. (The remaining meeting, for the advisory council of the National Institute of Child Health and Human Development, had already taken place on January 13, 2025, *i.e.*, seven days before the change in Administration.)

120. In total, over 250 grant-related meetings that had been scheduled for January and February 2025 via publications in the Federal Register were likewise cancelled after Inauguration Day—often with just a day's notice (and no notice of cancellation in the Federal Register). In contrast, in prior years cancellations and amendments to noticed meetings were rare. According to an analysis of Federal Register notices, only an average of four cancellation notices were issued each year between Fiscal Years 2010 and 2024, and even amendments—which typically provide a new date immediately—were uncommon, with an average of around 100 each year.

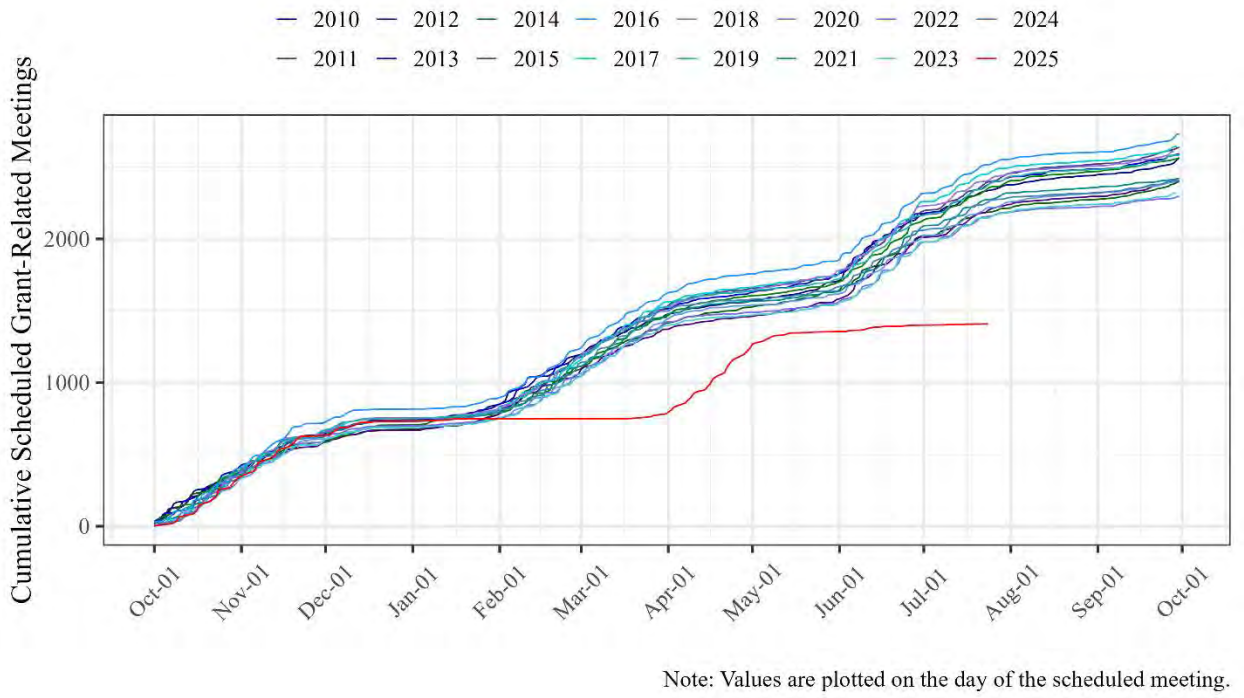
121. Between January 22 and March 3, defendants also suspended the scheduling of future advisory-council or study-section meetings; no notices for future meetings appeared in the Federal Register during that time. As discussed above, on January 21, Acting Secretary Fink issued the Notice Pause Directive, instructing among other things, that no notices be submitted for publication to the Federal Register unless approved by a presidential appointee.

122. On February 7, 2025, upon information and belief, an NIH official emailed a researcher that submissions to the Federal Register "are now on hold indefinitely." Throughout February (and continuing into March), multiple webpages from the NIH institutes stated: "At the present time, all Federal advisory committee meetings have been canceled until further notice. Additional information will be forthcoming as it becomes available. We apologize for any inconvenience."

123. Defendants resumed publishing notices of upcoming study-section and advisory-council meetings in the Federal Register in early March, but the number of meetings scheduled for this fiscal year remains at a level far below the number of such meetings in every fiscal year since 2010, and even further below the number that would be required to make up for the meetings not held in January and February.

124. Based on an analysis of notices posted in the Federal Register, defendants have held around 930 meetings to review grant applications in Fiscal Year 2025 to date. That represents a sharp and unprecedented drop from prior years. From Fiscal Years 2010 through 2024, NIH held between approximately 1,410 and 1,700 meetings over the same period, with an average of about 1,540. The Fiscal Year 2025 figure thus reflects a decline of nearly 40% relative to that historical baseline.

125. Despite the shortfalls and cancellations, defendants are not picking up the pace. As shown in the following figure, defendants remain well below the historical average meetings held, and the pace of new meetings scheduled from April to May is similar to that of previous years, when it would need to be substantially higher to make up the pace and spend the money appropriated by Congress:



Note: Values are plotted on the day of the scheduled meeting.

126. According to NIH's contemplated schedule, some Cycle II projects were to start in April 2025. For example, multiple UMass grant applications from Cycle II—with anticipated project start dates on or around April 1, 2025—received fundable scores from their study sections and yet remain in limbo because the relevant January advisory-council meeting was canceled.

127. Upon information and belief, the continued delays described in the preceding paragraphs directly result from the implementation of the Challenged Directives.

B. Delay and Withholding of Final Disposition of Awards

128. In addition to their frustration of the activity of study sections and advisory councils, defendants have also been systematically delaying and withholding final decisions on applications that have already received favorable scores and recommendations from the relevant study section and/or advisory council.

129. Upon information and belief, defendants maintained a total freeze on the issuance of new notices of award, including for non-competing renewals, from January 28, 2025, to February 28, 2025.

130. Defendants appear to no longer maintain a total freeze on the issuance of all new NOAs. However, upon information and belief, defendants are still delaying final decisions on applications in order to implement the Challenged Directives by conducting a review of applications for their relation to subjects and topics disfavored by the Administration. This review process has resulted in a delay on rendering final dispositions and award decisions on pending applications.

131. Upon information and belief, NIH's layoffs of the grant management, programmatic, and scientific staff that advance the grant application and peer review process have exacerbated, and will further exacerbate, these funding delays. NIHGPS §2.1.1, at I-44. The current Administration fired approximately 1,200 probationary workers at NIH, including those scientific, programmatic, and grant management staff members who worked directly on, and were

in charge of, grant approvals, renewals, and disbursements. HHS has started to lay off an additional 1,200 NIH employees.[29] A third round of layoffs is expected by September 30, 2025.[30]

132. In addition, upon information and belief, the recent layoffs included the directors of individual NIH institutes and centers who are responsible for signing off on final grant funding decisions. 42 U.S.C. §284(b)(3). On April 1, 2025, the directors, including acting directors, of the National Institute of Allergy and Infectious Diseases (NIAID), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institute on Minority Health and Health Disparities (NIMHD), the National Institute of Nursing Research (NINR), and National Human Genome Research Institute (NHGRI) either were placed on administrative leave or offered reassignment to the Indian Health Service in distant States. These institutes' directors were responsible for at least $9 billion in annual Congressional appropriations.[31] These layoffs appear targeted at institutes and centers either established by Congress for purposes that conflict with policies disfavored by the Administration, or which have conducted research on topics disfavored by the Administration.

133. As described in greater detail below (*see infra*, paragraphs 160-207), plaintiffs are awaiting a decision on hundreds of applications currently pending before the agency—including many applications that received favorable reviews from the relevant study section and/or advisory council. For ease of reference, this Amended Complaint refers to the pending applications just described as the "Delayed Applications."

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[29] Whyte L.E. *et al.*, *RFK Jr. Plans 10,000 Job Cuts in Major Restructuring of Health Department*, Wall Street J. (Mar. 27, 2025), https://www.wsj.com/politics/policy/rfk-jr-plans-10-000-job-cuts-in-major-restructuring-of-health-department-bdec28b0.

[30] Molteni M. *et al.*, *Five NIH Institute Directors and Numerous Lab Heads Ousted in Unprecedented Shake-up*, STAT (Apr. 2, 2025), https://www.statnews.com/2025/04/01/nih-rif-1200-layoffs-raise-concerns-health-medicine-biomedical-research.

[31] Kozlov M., *One of the Darkest Days': NIH Purges Agency Leadership amid Mass Layoffs*, Nature (Apr. 1, 2025), https://www.nature.com/articles/d41586-025-01016-z.

134. Upon information and belief, the continued delays described in the preceding paragraphs directly result from the implementation of the Challenged Directives.

C. Delay and Withholding of Renewal of Awards

135. Upon information and belief, the Challenged Directives have likewise governed NIH's review of applications for grant renewals by current grant recipients. Upon information and belief, defendants have required NIH staff to review grant renewal applications to determine whether they relate to subjects that are disfavored by the Administration, which itself has resulted in substantial delays in rendering decisions on applications for grant renewals.

136. As of April 1, plaintiffs are awaiting decision on non-competing renewals that otherwise meet the criteria for renewal but that defendants have declined to process in the ordinary course. For ease of reference, this Amended Complaint refers to the non-competing renewals just described as the "Delayed Renewals."

137. For example, as of April 1, University of Washington is experiencing delayed renewal of 73 grants totaling over $61 million. Some of these renewals have been delayed for months, with the resulting funding disruptions undermining the University's budgeting, forcing pauses in research, and requiring the University to resort to furloughs, staff reductions, and planned layoffs.

138. Upon information and belief, the continued delays described in the preceding paragraphs directly result from the implementation of the Challenged Directives.

D. Defendants' Removal of Notices of Funding Opportunities

139. Upon information and belief, no later than January 31, NIH's institutes and centers were informed that specific Notices of Funding Opportunity were being withdrawn and cancelled.

Similarly, upon information and belief, NIH only published three NOFOs between January 20 and March 26.[32]

140. The withdrawal of NOFOs continued on the grounds, *inter alia*, that the research opportunities involved DEI or gender.

141. The withdrawal of NOFOs occurred in the form of "unpublishing" the NOFOs, referred at times to the "disappearing" of NOFOs.

142. At least some of these NOFOs were withdrawn after grant applications had been submitted in response to them.

143. Upon information and belief, the removal of NOFOs described in the preceding paragraphs directly result from the implementation of the Challenged Directives.

IV. Defendants' Implementation of the Challenged Directives Through Termination of Already-Issued Grants

144. Defendants' implementation and enforcement of the Challenged Directives has also directly resulted in the termination of more than one hundred grants to plaintiffs' instrumentalities on the grounds that they relate to topics now blacklisted by the Challenged Directives. For ease of, this Amended Complaint refers to the terminated grants just described as the "Terminated Grants."

145. On or about February 10, NIH provided individual institutes with a list of grants that were to be terminated. Upon information and belief, the decision to terminate these grants was based on Acting Secretary Fink's Secretarial Directive and on direction from the Executive Office of the President.

[32] Reardon S., *Trump Officials Will Screen NIH Funding Opportunities*, Science (Mar. 26, 2025) (stating that "NIH only published three NOFOs between 20 January and 26 March, compared with 163 in 2023 and 147 in 2024 between the same dates"), https://www.science.org/content/article/trump-officials-will-screen-nih-funding-opportunities.

146. Upon information and belief, the lists of to-be-terminated grants provided by NIH to its individual institutes reflect list of grants to be terminated and template letters provided by HHS and personnel affiliated with the so-called Department of Government Efficiency (DOGE) to NIH. Upon information and belief, shortly after the change in Administration, personnel associated with the DOGE initiative obtained access to NIH's internal grants databases.

147. On February 28, a post on DOGE's official X account announced the cancellation of numerous NIH grants related to China, racial health disparities, and gender-affirming care:

148. The decision to terminate Diversity Supplements not only undermines Congress's and NIH's previously stated goal to promote diversity among scientists, but it also actively harms diverse candidates. This is because, until recently, NIH has been issuing NOFOs for workforce development grants in pairs, with both a "standard" NOFO and a "diversity" NOFO, allowing individuals to self-identify as diverse. But now that Diversity Supplements are being cancelled and not funded, people who identified as diverse in their applications are not even eligible for funding, while people who did not identify as diverse remain eligible.

149. Upon information and belief, on or about March 4, HHS identified additional NIH grants that were to be terminated based on the Challenged Directives, which NIH's Office of Extramural Research then communicated to the individual institutes.

150. Upon information and belief, on or about March 12, 2025, NIH provided staff at the individual institutes with a list of grants to be terminated, which were identified based on the factors identified in the Priorities Directive. NIH has used the Priorities Directive staff guidance to implement and assess the grant research portfolios of each of the ICs.

151. As already discussed, in the March 13 Award Revision Guidance, Michelle Bulls instructed the ICs' Chief Grants Management Officers on how to issue termination letters. Bulls instructed that termination letters should include the following language: "It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated." The instructions included the language that termination letters should include for the disfavored category on which the termination was based, including the following:

- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

- Gender: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

- Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in

ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

152. Upon information and belief, on or about March 14, Bulls met with the ICs' Chief Grants Management Officers and reported approximately 945 terminated grants. Bulls forwarded the grant terminations to ICs in batches for issuance of termination letters.

153. Upon information and belief, NIH has terminated more than 100 grants at plaintiffs' public institutions since January 20, 2025, in accordance with the Challenged Directives.

154. Plaintiffs' universities have received grant termination letters that include the boilerplate termination language provided by Bulls to the ICs.

155. These grants support a wide range of scientific inquiry and were awarded after a thorough review process for scientific merit, consistency with agency priorities, and other qualities.

156. Upon information and belief, actors outside NIH have identified the grants that should be terminated based on the Challenged Directives and their broad implementation, and the grants have been terminated without the input—and sometimes without the knowledge—of the NIH program officers who ordinarily manage the grants. In other words, NIH terminated these grants without consulting with the NIH career scientists with scientific knowledge about the research being funded.

157. Upon information and belief, to date, defendants have yet to identify any basis for its alleged priorities, as reflected in the Challenged Directives, other than the Executive Orders and the Administration's political views on certain subjects.

158. Upon information and belief, defendants have not made or finalized any change in NIH agency or IC priorities as identified in either the NIH's strategic plan or NIHGPS.

IMPACT OF THE CHALLENGED AGENCY ACTIONS

159. Institutions in each of the plaintiff states have experienced delays and other funding disruptions as a result of defendants' adoption, implementation, and enforcement of the Challenged Directives and the other acts and omissions described above.

I. Harms to Massachusetts

160. UMass has directly experienced harm as a result of defendants' treatment of the Delayed Applications.

161. As of March 31, 2025, UMass has 353 applications for NIH funding that are overdue for review based on NIH's published schedule of cycles. Of these, (a) 272 are awaiting study section review; (b) 43 have received fundable scores from study section review and are awaiting advisory council review; (c) 14 have received possibly fundable scores from study section review and are awaiting advisory council review; and (d) 18 have received fundable scores and been reviewed an advisory council but have not been notified of a final determination on funding. In total, $848,332,898 in sought funding is awaiting approval across all active applications, $133,234,318 of which is for projects that have already been scored as fundable.

162. A project entitled, "Elucidation of the mechanisms by which Ms4a genes regulate neurodegeneration in Alzheimer's Disease and related disorders," grant number R01AG089801, is representative of the delays UMass has experienced. One major obstacle of treating Alzheimer's disease is the paucity of genetic targets against which to direct therapeutic efforts; this project aims to investigate a recent and promising gene which could inform the development of new treatments for this and other neurodegenerative diseases. UMass researchers submitted the application for this grant on July 9, 2024, with an anticipated start date of April 1, 2025. Study section review placed it in the 13th percentile of all contemporaneous projects submitted to the IC, which has a payline of 17th percentile—thus, this was a fundable study with an overwhelming likelihood of

receiving funding. This project was scheduled for advisory council review on January 28, 2025; that session was canceled, then rescheduled for April 22, 2025, three weeks after the project was intended to begin. In preparation for the start date of this grant, UMass Chan Medical School hired two postdoctoral fellows, which is standard practice and timing for this manner of research. Additionally, a significant number of genetically modified mouse cell lines had to be bred and aged so that neurogenerative phenotypes would appear. Due to the delay in evaluating this grant, UMass must continue funding these preparatory steps well into the life of the project with the uncertainty that funding will arrive, or else scrap this promising research project entirely, foreclosing research into a promising area of new treatment for sufferers of Alzheimer's disease and related diseases.

163. Delays in funding decisions and evaluation of applications have already caused numerous and critical harms to UMass. Due to uncertainty of the funding of multiple projects ranked as fundable, UMass schools have made dramatic cuts to the size of programs that rely significantly on NIH support. UMass Chan Medical School has rescinded acceptances to the vast majority of students admitted to its PhD program in Biomedical Sciences, reducing that program from 70 to approximately 10. UMass Amherst has reduced Fall 2025 graduate admissions to its doctoral programs from 1099 admittees to 805, rescinding financial awards to 100 accepted applicants. UMass Medical School has arranged for emergency funding to continue paying stipends of current graduate students and post-baccalaureate scholars through June 30, 2025, but does not have emergency funds sufficient to replace those lost in terminated grants or to pay further costs associated with delayed grant awards. UMass Amherst will use available emergency funds to support students, staff, research faculty, and preservation of research materials for in-progress experiments until August 31, 2025, but projects that the funds will be exhausted by that date. This

relief is intended to soften the impacts to staff and research efforts but is incapable of replacing lost federal funding. These funds are being diverted from other important needs, such as deferred maintenance, strategic investments, and repayment of bond funds.

164. Additionally, numerous irreparable harms impend. Future recruitment of doctoral students, postdoctoral researchers, faculty, and staff will be negatively impacted by diminished funding. And without incoming streams of grant funds and the attached facilities costs used to oversee the research facilities which make these projects possible and economically viable, UMass will risk a reduced ability to meet existing obligations to repay bond funds used to construct those facilities. Any reduction in the university's bond rating will in turn increase the expense of augmenting research facilities in the future.

165. As a result of defendants' implementation and enforcement of the Challenged Directives, UMass has had at least five active grants and at least three additional passthrough awards terminated, without warning or cause, since March 21, 2025. UMass has also received "program cancellation notifications" related to three grants. Terminated grants include a study on the effects of the quality of behavioral health care on children, "Effect of Medicaid accountable care organizations on behavioral health care quality and outcomes for children," award number 3R01MH134176-02S1, funded for $99,974; and three studies aimed at understanding and reducing the spread of HIV amongst different vulnerable populations: "Optimizing an mHealth intervention to improve uptake and adherence of the HIV pre-exposure prophylaxis (PrEP) in vulnerable adolescents and emerging adults," award number 5R33HD107988-04, with an award of $278,952; "Adapting mHealth interventions to improve self-management of HIV and substance use among emerging adults in Zambia," award number 5R34MH124081-02, with an award of $671,459; and "Applying deep learning for predicting retention in PrEP care and effective PrEP use among key

populations at risk for HIV in Thailand," award number 5R03MH130275-02, with an award of $76,214. In the two other terminated grants—"Faithful response II: COVID-19 rapid test-to-treat with African American churches," award number U01MD018310, with an award of approximately $126,000; and "Training the long-term services and supports dementia care workforce in provision of care to sexual and gender minority residents," award number 3R01AG075734-02S1, with an award of approximately $65,000—UMass was the subawardee.

166. UMass has also had ten applications for grants summarily denied without any form of scientific review. These include grants submitted in response to subsequently withdrawn NOFOs, including PAR-23-271, PAR-21-358, and PAR-24-077.

II. Harms to California

167. California has experienced direct and irreparable harm as a result of the Challenged Directives. Disruptions in the conduct of biomedical research and training in California directly impact the employment and economic well-being of the biotechnology and pharmaceutical industries headquartered in California. NIH grant terminations and funding delays have deterred prospective students and faculty who would have otherwise worked at universities and companies in California. Also, California has a direct interest in the health and safety of its residents, the prevention of both chronic and communicable diseases in the State, and in the State's economic wellbeing. The termination of NIH funding into research interventions to prevent or treat the spread of HIV/AIDS, sexually transmitted illnesses, COVID-19, and other virus families of pandemic concern—including diseases of emerging concern such as Dengue, Chikungunya, and Zika—and shingles, increases the risk of and incidence of these diseases in California. The terminations resulting from the enforcement of the Challenged Directives have specifically targeted some of the most vulnerable Californians, including women experiencing domestic violence, children at risk of suicide, and minorities at a higher risk of chronic or infectious diseases.

168. Since February 20, 2025, as a result of the Challenged Directives, UC has had at least 52 NIH grants terminated, amounting to over $37 million. The impact on UC Health Centers like UCSF that conduct clinical trials, its researchers, and the larger research community have been substantial. When UCSF receives a research grant from the NIH, the funds must be used to support the specific research project identified in the grant consistent with the terms of the notice of award. The grant funds are used to support all aspects of the grant, including personnel costs, drug and medication costs, technology, and equipment. When a grant is terminated, there are no longer any funds available to pay the salaries of the research staff or to cover significant expenses. When research staff are laid off, the institution loses the knowledge and experience those research staff members possess and that was attained through the research project. Once canceled, most research projects cannot immediately resume. Many of these projects entail longitudinal studies. When scientific studies stop in full swing, their partial results often lose validity.

169. Among these terminations apparently for "gender identity" and "vaccine hesitancy" are studies key for understanding the health of all Americans. They included a grant for a UC Davis research project investigating the biological risk factors for dementia among target populations with early signs of cognitive dysfunction, including white, Hispanic, and black participants that had already enrolled over 1,700 participants, and a grant to UCSF Professor Nisha Acharya who studied the effectiveness and potential adverse effects of a vaccine for shingles, a disease that one in three Americans are likely to develop in their lifetimes that cancelled $1,248,374 in funding. A third study involved the study of doxycycline, a common antibiotic used to treat sexually transmitted diseases and serious infections; defendants cancelled $3,243,539 in funding. The doxycycline study assesses the metabolization of the drug in men and women, supporting insights into whether microbial resistance will undercut the utility of the drug. While

the study, consistent with prior NIH policy, allows transgender individuals to participate, the focus of the study was not on gender identity. The harms from these terminations underscore the damage that flow from the abrupt nature of defendants' terminations. Safety monitoring during and after doxycycline dosing is critical to protecting the safety of participants already enrolled in the study. Doxycycline may cause liver injury and allergic reactions days to weeks after administration of the drug. As a result of these terminations, UCSF is preparing to lay off the staff members responsible for clinical monitoring, full-time postdoctoral researchers responsible for analyzing research data, and is unable to pay salary owed to senior scientists and principal researcher for research. Thus, these categorical terminations have already caused numerous and critical harms to the UC.

170. The delays in funding decisions and evaluation of applications have further harmed the UC system. First, the UC system has instituted a system-wide hiring freeze on new faculty and staff. Top-ranked departments across UC campuses in chemistry, biology, public health, and more may reduce their graduate student classes. UC departments have had to consider rescinding offers of funding to some students admitted to doctoral programs. The expected grant funds are also necessary to the research facilities that make these projects possible and economically viable.

171. Second, the delays in funding and terminations harm the UC's educational and research mission. Doctoral students, postdoctoral researchers, faculty, and staff from around the world collaborate with or come to California to join the UC research enterprise. Future recruitment of these young scientists and researchers will be negatively impacted by diminished funding and arbitrary terminations aimed at international collaboration and research projects. Further, terminations have specifically impacted the communities that come to the UC system for clinical trials and other community health interventions. Midstream terminations of long-term projects

meant to reduce health disparities in projects like maternal mortality, the spread of HIV/AIDS, and services to other underserved communities directly undermines the trust necessary to convince individuals to participate in UC research projects.

172. Since February 20, 2025, the CSU has received over 17 termination notices, including 5 where it serves as the primary awardee. They collectively amount to a loss of over $20.2 million in budgeted funding to the CSU, but CSU estimates the number may be much higher as grants continue to be cancelled. One of its universities, San Diego State University (SDSU) alone currently has 23 non-competing renewals pending action by the grants office to authorize the next segment of funding, 34 new proposals and competing renewals totaling approximate $16 million awaiting NIH study section review, and 10 new proposals and competing renewals totaling approximately $3.2 million that received fundable scores awaiting NIH advisory council and Notice of Award.

173. Unless funding of each NIH grant is restored to each of the affected CSU university campuses, neither the California State University nor any of its auxiliary organizations will have the financial resources to keep the research programs running. Neither does the CSU's operating budget have any available funds to cover these programs, should additional federal funding be terminated. The CSU's operating budget has two main funding sources: the state General Fund (as appropriated by the Legislature annually) and student tuition and fees to cover the educational budget. Due to ongoing gaps in annual funding, the CSU system has in past years already had to reduce student enrollment and suspend degree programs. However, because the statutory purpose of CSU to provide education to all qualified Californians, CSU does not have the discretionary option not to spend its funds as required to fulfill its educational mission. There is hence no

additional funding available to cover another $20 million in lost NIH grant program funding which, up to this point, has been reliably predictable as a funding source over multiple years.

174. NIH terminations are particularly egregious when budget planning must be done years in advance. CSU's education budget includes many items that are based on long-term commitments and planning efforts, including phased campus development under multi-year master plans, deferred maintenance schedules, and bond financing repayments. These funds are already committed are not available to replace lost funds from the NIH programs. NIH grant funding is also sought and secured well in advance of its use, necessitating personnel and equipment purchases based on those commitments.

175. Over the last fifteen years, CSU campuses have made concerted investments in student training, faculty hiring, and institutional support of medical and public health research. Delays in NIH funding decisions and evaluation of applications and terminations now endanger all of those efforts. SDSU, for example, has instituted a hiring freeze on new faculty and staff, and will now defer long-term research projects. Terminations over grants studying health disparities and sexual and minority health have directly impacted the salaries of SDSU staff, faculty, and students. Without NIH funding, some students may need to discontinue their studies and in the case of international students, leave the country.

176. The damage from grant terminations to CSU campuses' relationship with the surrounding community and patients is similarly irreparable. For example, federally funded studies establish that sexual and gender minority youth are at a higher risk of suicide and suicide ideation.[33] Yet one of the grants terminated funded suicide prevention services to sexual and

[33] Luk J.W. *et al.*, *Sexual Minority Status and Age of Onset of Adolescent Suicide Ideation and Behavior*, 148 Pediatrics, no. 4 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC9446478.

gender minority youth, and was terminated in the middle of their multi-year period without any opportunity to bridge individuals at high-risk of suicide to new services providers.

177. CSU campuses to date have received no funding or direction from NIH concerning the participants enrolled in terminated trials even where the potential for increased suicide attempts and subsequent death is high because every single participant in a study is at high risk for suicide. This is particularly damaging to CSU's relationship with the community health providers that often support enrollment in intervention studies.

178. The termination of the grants often means that researchers cannot fully evaluate whether an intervention is statistically effective—essentially wasting the valuable resources already expended and delaying scientific progress, stifling innovation, and impeding the development of new medical treatments, technologies, and public health initiatives.

179. Grant terminations, especially without warning, are also directly affecting students at the CSU. Graduate students, who are at the core of research laboratories, rely on NIH grants not only for resources to support research, but also for their own stipends, tuition support, and training programs. Sudden cuts have immediate and consequential impacts to these students, who often live paycheck to paycheck, putting their housing and basic needs at risk.

180. NIH grants also support undergraduate students at CSU. For example, the CSU U-RISE program is funded through a grant from the National Institute of General Medical Sciences and is meant to broaden perspectives in future scientific and biomedical research by identifying students' interest in pursuing research as a career and by providing training opportunities to be competitive for entering graduate programs. Students accepted into the U-RISE program receive trainee stipends to defray living expenses during research training experiences, and also support student trainee travel expenses to attend scientific meetings with their mentors and help defray

university personnel expenses and supplies. At least 9 CSU universities received a notice from NIH stating that the university must "cease project activities as of the current budget period end date of 3/31/2025," and as a result these 9 CSU universities must immediately terminate stipends for students in the middle of the semester, causing participating students direct and significant harm, as their financial aid packages account for U-RISE stipends.

181. The impact from the termination of grants funding training programs like U-RISE is also profound. It inflicts emotional and academic distress upon students, damaging the pipeline of future researchers. The CSU, with limited resources, bears a disproportionate burden, exacerbating financial strain and competitive disadvantages.

182. At this point, delays in the review of NIH grant applications have also prevented the researchers from planning for the implementation of the grants and stalled important research programs from moving forward at multiple CSU campuses.

183. A five-year grant designed for universities without significant NIH funding that serve historically underrepresented student populations in communities with significant populations with unmet health needs in Fresno, California, has been delayed multiple times in its review and currently has no advisory-council review date. A grant of this size requires many people working collaboratively. The grant application has 12 staff associated with it. Faculty working on this grant will receive time released from teaching ranging from 25 percent to 50 percent but cannot plan for this while the grant remains under review with changing implementation dates.

184. Another five-year grant intended to study how cells differentiate themselves for specific uses, which would advance the understanding of certain genetically linked illnesses, has similarly been delayed. The proposal was written and submitted with review guidelines and

criteria that has since been changed after the grant has been submitted. Delays in review have similarly delayed graduate student hiring associated with the grant.

III. Harms to Maryland

185. Delays in the grant review process and terminations of existing grants have disrupted valuable research at Maryland's research universities.

186. UMB has nearly 500 proposals totaling $1.1 billion in the NIH review pipeline. This includes 380 proposals totaling $1.04 billion awaiting study section review, 32 proposals totaling $21.4 million that received fundable scores and are awaiting advisory council review, 12 proposals totaling $37.5 million that received fundable scores and have been reviewed by NIH advisory councils, and 44 proposals totaling $33.2 million that received possibly fundable scores and are awaiting advisory council review. UMCP has approximately 200 proposals pending with NIH, totaling about $354 million.

187. The delays in the review process have harmed the universities in myriad ways, disrupting ongoing research, interfering with planning and budgeting, forcing the universities to divert resources from other needs, and restricting their ability to accept new graduate students and recruit and retain quality research trainees. The delays also directly harm patients and the public. Among the UMB studies that are stalled in the review process despite having already received fundable scores and undergone advisory council review are a clinical trial involving assisted living residents with Alzheimer's disease and related dementias and another study that seeks to assist selection of antidiabetic drugs for individual patients. One of UMCP's stalled submissions is the Bucharest Early Intervention Project, a landmark child development study that has followed a group of individuals, some of whom were raised in institutions, for more than 20 years. The study was reviewed by a study section in October 2024 and received a score of 12th percentile, but advisory council review has since been delayed three times.

188. Arbitrary grant terminations have also devastated research at UMB and UMCP. UMB has received termination notices for 14 NIH awards representing about $33 million in lost research funding. One terminated grant funded a study at UMB involving more than 1,000 human subjects who underwent diagnostic tests as part of the funded study. The human subjects consented to the study based on the understanding that they would be provided with test results that could be important to their health. The abrupt termination of the grant takes away federal funding for providing subjects with those test results. Another affected UMB project examined differences in brain and hormonal mechanisms between males and females in relation to pain conditions. The project earned the highest score in its study section. UMCP has received notice of termination of nine grants, representing about $1 million in lost research funding. Examples of the affected studies include a study examining alcohol use among sexual orientation and gender identity minority youth and another study assessing the needs of persons who suffer biological disorders in sex development.

IV. Harms to Washington

189. The University of Washington has experienced significant harms as a result of defendants' implementation of the Challenged Directives.

190. As of April 1, the University of Washington has more than 500 proposals awaiting NIH study section review. It has 54 proposals for $138 million in total funding requested that received fundable scores, awaiting NIH advisory council and Notice of Award. And it has 76 proposals for $260 million in total funding requested with fundable scores that for which the NIH advisory council has met or voted electronically to approve a grant for funding, but the NOA has not yet been issued.

191. Additionally, the University of Washington has 73 overdue non-competing renewals totaling over $61 million that have yet to receive NOAs. Delays in this funding has

already had potentially irreversible effects on the University of Washington. To take just one example, the University of Washington's Institute of Translational Health Sciences (ITHS) has been awaiting an overdue non-competing renewal on a $10.5 million annual grant for over a month.

192. ITHS is a partnership between the University of Washington, Fred Hutchinson Cancer Center, Seattle Children's, and regional institutions to promote the translation of scientific discovery to clinical practice. One example of the innovative work performed at ITHS is the Gene & Cell Therapy Lab's (GCTL) accelerated development of a therapy to treat advanced ovarian cancer, called UltraCAR-T Cell therapy. Scientists in the GCTL worked with a biopharmaceutical company to transfer the technology so that the product could be made quickly and effectively. A separate unit of ITHS, the Translational Research Unit, conducted the rigorous clinical trials necessary to advance the technology towards a clinical use. But now, without funding for over thirty days, the University of Washington has been forced to institute staff reductions, furloughs, and elimination of positions at ITHS.

193. Other important research centers that are at risk because of delays in the grants review and award processes at NIH include the University of Washington's Alzheimer's Disease Research Center (ADRC), the Nathan Shock Center of Excellence (NSC) in the Basic Biology of Aging, and the joint University of Washington /Allen Center. These Centers are funded by the National Institute on Aging (NIA) and received excellent scores during their reviews in study section in the fall. Because the NIA Council did not meet as scheduled in the January, these large grants were not approved for award. They all end in April or May and would leave large research teams without support. The work being done by these centers is longitudinal and lapse in funding will mean loss of critical cohorts that have been studied in some cases up to 40 years.

194. On top of these, University of Washington researchers have also had at least 11 grants terminated by NIH, totaling over $3 million to support innovative work in trauma research for victims of sexual assault, prevention of chlamydia infections, and the impact of air pollution on Alzheimer's disease and related dementias, among other topics.

195. The implementation of the Challenged Directives, and the resulting delays and terminations, have not only disrupted this critical research, they have also led to University-wide harms. The failure of NIH to communicate deviation from the normal funding application cycle for reviews and approval of funding means that research team which often plan grant applications years in advance to maintain necessary funding to support their research teams are left without consistent funding and in some cases are needing to furlough or layoff research team members. The University of Washington has paused some new hires whose research programs depend on timely NIH awards, including several where candidate interviews were already underway, and programs have been forced to reduce graduate admissions between 25 and 50%. Moreover, the terminations, delays, and unprecedented disruptions in funding have had a profoundly negative effect on morale University wide. Faculty and staff don't know if their funding will be cut, if their research will be terminated, whether they will be able to attend conference, or even whether they will continue to have jobs. The stress of these funding disruptions is palpable and has negatively affected the University of Washington's mission. Research staff that are stressed about losing their jobs on a daily basis are not able to focus their full creative energy on innovation and discovery.

V. Harms to the Remaining Plaintiffs

196. In Arizona, five of Arizona State University's NIH-funded projects have been paused or terminated, and the university continues to receive new grant-related notices on an ongoing basis. Arizona State University has more than 450 proposals with an estimated amount

of $771 million that have been submitted to NIH but for which it has not received a response. Northern Arizona University received a termination notification of an award, "*Bridging Arizona Native American Students to Bachelor Degrees*," which funds a transfer program of students from two-year associate degree programs at Coconino Community College to four-year baccalaureate degree programs at Northern Arizona University. This program will cease for current students, jeopardizing the likelihood that they transfer to Northern Arizona University and complete a baccalaureate degree. Northern Arizona University will forgo recruitment of the final cohort of students who would have benefitted from this program, and program activities will cease on July 31, 2025. Northern Arizona University has 34 proposals, representing approximately $47 million, submitted to NIH for which it has not received a response.

197. CU Anschutz is Colorado's only public academic medical center. CU Anschutz has more than 500 research laboratories on campus pursuing their research mission. This work supports important basic science and clinical research, graduate students, clinical trials, and other work in a broad array of areas on the health spectrum. Currently, 479 doctoral graduate students are reliant on the grant funding of the institution to complete their education and work toward finding new discoveries. Upon information and belief, because of NIH's actions, CU Anschutz has experienced direct harm, including but not limited to (a) a 23% decline in NIH grant awards for the period of time from January through March 2025 as compared to the period of time from January through March 2024, and (b) termination of numerous existing grant awards. CU Anschutz has received 18 NIH grant terminations to date with a total loss of funds of at least $8,455,794.17. CU is a direct grantee of seven of those grants, totaling $2,921,217.25 in funding loss. These grants would have funded CU Anschutz's continued work on a variety of health studies including hormones, vaccines, Alzheimer's disease and other important studies. CU is a

subgrantee on 11 additional grants terminated by NIH, totaling a funding loss of at least $5,534,576.92. These grants would have continued to fund CU Anschutz's work and partnership with their grant sponsors on work related to antiviral measures, impact of environmental toxicants on diabetes, and adolescent medicine trials for HIV/AIDS interventions, among other studies.

198. The University of Delaware has directly experienced harm as a result of defendants' treatment of the Delayed Applications. As of March 31, 2025, the University of Delaware has (a) 77 proposals totaling $177 million awaiting NIH study section review; (b) at least 13 proposals totaling $59.8 million that received fundable scores, awaiting NIH advisory council and Notice of Award; and (c) 102 proposals totaling $234.9 million that received possibly fundable scores, awaiting NIH advisory council and Notice of Award. "Since late January 2025, the University of Delaware has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed." The University of Delaware uses information regarding NIH grant applications and award rates to inform its graduate admissions process. Due to uncertainty of incoming grant funding related to the delays in reviewing and awarding grants by NIH, the various PhD programs at the University of Delaware that rely on NIH funding for graduate student support have reduced admission offers for their incoming class of graduate students by up to 50%. Such instability in funding is affecting the recruitment and retention of high-caliber quality research trainees. The inability to retain quality research trainees will have ongoing effects on the research capabilities of the University of Delaware, including by limiting the individuals qualified to conduct certain research. The delays have disrupted ongoing research, as well as actively setting back the University of Delaware's ability to conduct critical research now and in the future. Funding gaps have already forced

researchers to abandon promising studies, miss key deadlines, or lose highly trained personnel. Some of these studies involve the use of animal test subjects, all of which would need to be terminated due to loss of funding. This results in not only ethical and financial losses but also wasted scientific opportunity, as experiments cannot simply be restarted once interrupted. In many cases, there is no way to recover the lost time, research continuity, or training value for graduate students and postdoctoral researchers once disrupted. Promising discoveries may be delayed indefinitely, and, in some cases, entirely lost.

199. Between March 21 and 31, 2025, the University of Hawai‘i received two notices of cancellation of direct NIH grants. The affected grants total approximately $344,000. In addition, since late January of 2025, pending University of Hawai‘i grant applications have experienced unusual delays resulting in substantial uncertainty. As of March 30, 2025, the University of Hawai‘i had approximately 65 proposals awaiting NIH study section review. As of the same date, the University of Hawai‘i had 31 proposals that received fundable scores but are awaiting NIH advisory council review and a final decision whether to award the grant. These unusual delays in NIH processing are affecting University of Hawai‘i budgeting and planning for fiscal year 2025-2026, creating uncertainty around department budgets, teacher workload, and the hiring of additional faculty, teaching assistants and graduate assistants. Although University of Hawai‘i has deployed bridge funding for impacted students, those resources are limited. Long-term use of non-federal funding is not a viable option.

200. In Minnesota, the University of Minnesota has had 21 NIH grants and subawards terminated. The terminations will result in the loss of approximately $8.5 million in research money to the University. In addition, NIH’s delay and/or cancellation of study sections have had a negative impact because significant numbers of grant proposals due for funding have remained

unfunded for at least one grant cycle, and they will potentially be unfunded indefinitely. These actions have been very disruptive to the University of Minnesota's ongoing research—including research involving clinical trials for life-saving medications or procedures. For example, the University of Minnesota is a major partner in the NIH U01 Diabetes Prevention Programs Outcomes Study (DPPOS), serving as the central biochemistry lab for 25 clinical sites and serving on the project's Steering Committee. This project addresses the National Alzheimer's Project Act's goal to "prevent, halt or reverse Alzheimer's Disease" in the high-risk group of persons with pre-diabetes and type 2 diabetes, who represent over half of the population aged 60 years or older in the United States. The terminations and delays threaten the University of Minnesota's ability to proceed with important projects like DPPOS.

201. As the result of three grant terminations, the University of Nevada, Las Vegas, has lost $2.4 million in research funding that supports projects focusing on, and advancing research related to, Alzheimer's disease. The funding losses limit access to research and findings on Alzheimer's disease. These grant terminations harm Nevada by defunding critical research that advances public health and educational opportunities in Nevada. And although the University of Nevada, Reno, has not reported receipt of any grant terminations, ongoing delays in review of numerous research proposals are negatively impacting the University's recruitment and retention efforts. This includes having to pause ongoing efforts to onboard new hires after the University had already provided those individuals with offer letters for positions with research programs that depend on timely NIH awards.

202. In New Jersey, Rutgers has directly experienced harm stemming from its pursuit of scientific research blacklisted by defendants, specifically studies with a perceived connection to DEI and COVID. As of April 10, 2025, faculty and staff at Rutgers have received termination

notices for at least six NIH grants, resulting in a loss of more than $7 million in funding. Rutgers will be unable to reallocate funds to offset these federal grant losses, triggering numerous irreparable harms. Ongoing experiments have stopped, suspending hiring and reducing staff research hours—all due to research perceived to be related to DEI and/or COVID. Such terminated grants relate to studies regarding HIV prevention, mental health, suicidal ideation, HPV vaccines, and COVID antiretroviral treatment. More broadly, the Challenged Directives have resulted in the cancellation of programs funded by NIH grants directed at supporting minority and underrepresented students pursuing training and graduate degrees in biomedical sciences and engineering at Rutgers, NJIT, and Kean—with NJIT and Kean losing approximately $1.2 million, respectively, as a result. Undergraduates at these institutions will lose out on opportunities to train in research excellence, unite in a diverse cohort to build identity, and prepare for the next phase of their biomedical research career pathway. In addition, since late January of 2025, pending grant applications at Rutgers, Kean, and NJIT have experienced unusual delays resulting in substantial uncertainty. As of April 11, 2025, Rutgers has approximately 13 proposals totaling $26,990,860 awaiting NIH study-section review; approximately six proposals totaling $19,608,265 that received fundable scores, awaiting NIH advisory-council review and Notice of Award; and 738 grant submissions under sponsor review with a total value of $1,387,066,143. As of April 11, 2025, NJIT has approximately 40 proposals totaling $70,683,171.27 awaiting NIH study-section review; 4 proposals totaling $3,269,729.47 that received fundable scores, awaiting NIH advisory-council review and Notice of Award; and 17 proposals totaling $26,602,999.51 that received possibly fundable scores, awaiting NIH advisory-council review and Notice of Award. As of April 11, 2025, Kean has six proposals totaling approximately $11 million awaiting NIH study-section review, advisory-council review and/or Notice of Award. These unusual delays in NIH processing

are affecting budgeting and planning for fiscal year 2025 at Rutgers, NJIT, and Kean, creating uncertainty around department budgets, teacher workload, and the hiring of additional faculty, teaching assistants and graduate assistants.

203. In New Mexico, NIH has terminated four research training grants at UNM representing over $9 million in lost research funding. These prestigious grants support vital biomedical workforce development programs that provide advanced training for UNM's students: (a) the Institutional Research and Academic Career Development Award (IRACDA) Post-Doctoral program trains post-doctoral fellows for research and teaching careers in academia; (b) the Leading Equity and Diversity in the Medical Scientist Training Program (LEAD MSTP) supports biomedical research training of UNM's MD/PhD students for developing the clinical research workforce, (c) the Initiative to Maximize Student Diversity at the University of New Mexico Health Sciences (IMSD) grant supports predoctoral trainees in the Biomedical Sciences Graduate Program and (d) the Undergraduate Research Initiative for Student Enhancement (U-RISE) trains and prepares undergraduate students for doctoral programs and careers in biomedical research. These training grants provide structured training and mentorship programs as well as financial support, including tuition and stipends, to advance students' education and career opportunities in biomedical research. UNM currently has approximately 50 students enrolled at different stages in these programs. Some of these programs have been at UNM for over 20 years. The aim of these training grants is to develop a group of professionals equipped with the technical, operational, and professional skills necessary for success as biomedical scientists, building capacity for groundbreaking research in New Mexico and representing our state's population in the biomedical workforce. At NMSU, NIH has terminated three research grants representing approximately $6.7 million in lost research funding. All three grants that were terminated funded

and promoted students' participation in the biomedical workforce by strengthening research training and preparing students for a successful transition into higher level biomedical degree programs and the biomedical workforce. NIH's termination of these grants impedes New Mexico's ability to continue developing breakthrough biomedical research and innovations.

204. SUNY has experienced direct harm as a result of the delays and terminations of NIH grants. For example, NIH had committed to five years of funding—a total of $3,596,263—for a project that established a center to train and develop health equity researchers focused on health disparities in and around Buffalo. The grant had met and exceeded all of its milestones, but it was terminated on March 28, 2025. NIH also canceled grants funding research into HIV treatment and care in Ghana; the impact of peer victimization on health outcomes for LGBQ+ youth; improving inclusivity of Alzheimer's disease research; and cardiovascular disease risks among sexual and gender minorities. Additionally, SUNY has been harmed by unexplained delays and procedural breakdowns. The uncertainty has led to reduced staff hours and other harms.

205. In Oregon, OHSU has experienced both NIH grant notices of terminations and delays in the processing of grant applications. Since March 24, 2025, OHSU received notices of termination of one NIH grant awarded directly to OHSU and seven NIH grants awarded to other institutions that issued subawards to OHSU. These terminations will result in the loss of $2.4 million in research funds to OHSU. OHSU has also experienced significant delay in its NIH application processing since January 2025. As of March 31, OHSU has approximately 280 proposals totaling over $730 million awaiting NIH study section review. As of March 31, OHSU has 70 proposals that received fundable scores totaling $172.4 million awaiting NIH advisory council meetings and notices of award. And it has 90 proposals that received possibly fundable scores totaling $194.9 million awaiting NIH advisory council meetings and notices of award.

These terminations and delays have disrupted ongoing research, graduate admissions processes, recruitment of key research personnel, and OHSU's ability to plan its operations. In many cases, once a study is disrupted, it is impossible to recover the lost time, research continuity, or training value of the study. As a result, studies with the potential to achieve breakthroughs in different disciplines and advance public health will simply not occur.

206. In Rhode Island, as a result of defendants' implementation and enforcement of the Challenged Directives, NIH has terminated two research grants at URI representing $3.7 million in lost research funding. One grant funded innovative research that was aimed at advancing the public health of those living with HIV by contributing to the investigation of causal mechanisms among networks of populations at high risk for HIV infection compounded by illicit substance use. The other grant funded the University of Rhode Island's ESTEEMED Scholars Program, a program that provides students from underrepresented backgrounds with the skills and resources necessary to pursue advanced education and degree programs in bioengineering and related disciplines. The impact on student achievement and the inclusive environment at URI will be hit particularly hard. Without URI ESTEEMED, several of the current trainees would have had to drop out of URI due to the lack of academic support the program provided and the stipend that allowed them to focus on their academics and research instead of working an outside job. These grants funded research aimed at advancing public health research for some of the most vulnerable in Rhode Island and allowing those from underrepresented backgrounds unparalleled academic opportunities. NIH's termination of these grants harms Rhode Island by defunding research that advances public health and educational opportunities.

207. In Wisconsin, as of March 31, 2025, NIH has terminated four research grants to UW-Madison. The total amount of funding anticipated under these awards is $25,149,959, and of

that amount, $12,631,870 has not been disbursed to UW-Madison. These grants are to fund research on infectious disease, vaccine development, minority health disparities, and child health and human development. NIH has also terminated two research grants funding research at UW-Milwaukee regarding substance abuse, violence, and suicide prevention. In addition, since late January 2025, UW-Madison has seen an unusual number of delays in the processing of NIH grant applications, rendering institution-wide budgetary planning especially difficult as the budget process at UW-Madison relies upon the NIH grant application, review, and approval cycle. Delays in the review of pending grant applications creates uncertainty and disrupts the funding cycle necessary to maintain continuity of research projects and consistent staffing of trained researchers. In many cases, there is no way to recover the lost time, research continuity, or training value once research is disrupted. Some researchers at UW-Madison have already been unable to commit to bringing on graduate students or maintaining current trainees due to funding uncertainty, and if funding that historically would have been expected is not forthcoming, or funding is indeed terminated, certain research projects will need to be abandoned. For one particular award—an NIH Research Program Grant (P01) supporting three co-investigators—termination with no funding alternative would necessitate the termination of ten research staff (including a postdoctoral trainee) and interrupt the progress of forty undergraduate, graduate, and medical students towards their degrees. NIH's delays and/or cancellations of study sections and advisory council meetings and grant terminations have thus harmed Wisconsin's universities. These actions further harm Wisconsin through the likely reduction of the future scientific workforce and by depriving Wisconsin and the broader community of critical biomedical research.

VI. Impact on Appropriated Funds

208. Notwithstanding Congress's appropriation to NIH, as a result of the implementation and enforcement of the Challenged Directives as described above, NIH has not

awarded billions of dollars in appropriated funding, with only a few months left of available funding.

209. Based on the publicly available NIH RePORTER database, in Weeks 4-11 of 2024 (*i.e.*, January 20, 2024, through March 14, 2024), NIH awarded a total of $4.08 billion to 8,071 projects. By comparison, in Weeks 4-11 of 2025 (*i.e.*, January 20, 2025 through March 14, 2025), NIH awarded a total of $2.45 billion to 4,961 projects—a reduction of approximately 40%.

210. Narrowing the focus to awards (and competing renewals) that require study section and advisory council review prior to award, in those same weeks, NIH awarded $740 million to 1,756 projects in 2024 but only $360 million to 781 projects in 2025. Focusing further still just on Weeks 6-11, the comparison is even more striking: 1,342 projects for $576 million in 2024, compared with 395 projects for $180 million in 2025, a reduction of nearly 70%.

211. The impact on appropriated funds continues to worsen. Looking at multi-year grant awards with April 1 budget start dates, the estimated difference for Weeks 12-13 (*i.e.*, the period from March 14, 2025, to April 1, 2025) is $1.04 billion. Of this, $780 million is due to non-competitive renewal awards that were anticipatable during this period—since many grants were due for renewal by April 1, 2025. In addition, based on the new and competitive renewal awards made during this same period in 2023 and 2024, there is a $260 million reduction in anticipatable new and competitive renewal awards in 2025.

CAUSES OF ACTION

Count 1—Against All Defendants
Administrative Procedure Act, 5 U.S.C. §706(2): Agency Action Contrary to Statute

212. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

213. The APA requires a court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. §706(2)(C), or "otherwise not in accordance with law," *id.* §706(2)(A).

214. In reviewing agency action, a court cannot accept "the agency's policy judgments . . . if they conflict with the policy judgments that undergird the statutory scheme." *Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 416 (D.C. Cir. 1994); *see Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 176 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000) (explaining that "federal agencies" cannot "substitute their policy judgments for those of Congress").

215. The Challenged Directives adopt, as a matter of final agency policy, the determination that projects with a perceived connection to "DEI" and other blacklisted topics "no longer effectuate[] agency priorities." The Challenged Directives order defendants not to fund projects with a perceived connection to those blacklisted topics, resulting in the elimination of funding opportunities, disruption of pending applications, and termination of ongoing grants described above.

216. The Challenged Directives are contrary to law and beyond statutory authority because they defy Congress's statutory directives to NIH to support research through publicly promulgated priorities, including those directed to "DEI."

217. Specifically, the Challenged Directives defy statutory directives requiring NIH and its respective ICs to encourage and support research and authorizing them to make grants to institutions and researchers for that purpose, *see* 42 U.S.C. §284(b)(1) (A), (b)(2)(A), as well as statutory directives requiring the NIH Director to, for example, "encourage efforts to improve

research related to the health of sexual and gender minority populations," in conducting and supporting research. *Id.* §283p.

218. The Challenged Directives also defy statutory directives that require NIH to articulate its priorities via the NIH Strategic Plan, which NIH must develop, submit to the appropriate Committees of Congress, and post publicly. *See* 42 U.S.C. §282(m)(1).

219. The Challenged Directives are also contrary to law because they defy Congress's consistent appropriation of funding to NIH's Institutes and Centers to carry out their respective statutory purposes and public priorities. NIH is flouting its statutory responsibilities by terminating so many grants with a dwindling opportunity to reallocate them, which will result in a substantial portion of Congress's appropriation going unspent. The Challenged Directives are therefore contrary to the statutes authorizing and appropriating funds for NIH research and beyond defendants' statutory authority.

220. Accordingly, plaintiffs are entitled to an order and judgment, and to a preliminary and permanent injunction, holding unlawful and setting aside the Challenged Directives and enjoining any action taken to enforce or implement the Challenged Directives.

Count 2—Against All Defendants
Administrative Procedure Act, 5 U.S.C. §706(2):
Agency Action Contrary to Regulation

221. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

222. The APA authorizes a court to "hold unlawful and set aside agency action, findings, and conclusions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and/or "without observance of procedure required by law." 5 U.S.C. §706(2).

223. As discussed above, the Challenged Directives instruct defendants to take adverse action on research projects with a perceived connection to blacklisted subjects under 2 CFR §200.340(a)(2) (2020). However, that regulation does not apply here and does not authorize the termination of any ongoing grants because (1) HHS-specific regulations, not §200.340, govern the termination of NIH awards, and (2) neither 2 C.F.R. §200.340(a)(2) nor 2 C.F.R. §200.340(a)(4) independently authorizes an awarding agency to terminate awarded grants on the grounds that NIH identified "agency priorities" after the award of the grant which the grant does not effectuate.

224. Accordingly, plaintiffs are entitled to an order and judgment, and to a preliminary and permanent injunction, holding unlawful and setting aside the Challenged Directives, and enjoining any action taken to enforce or implement the Challenged Directives.

Count 3—Against All Defendants
Administrative Procedure Act, 5 U.S.C. §706(2):
Arbitrary and Capricious Agency Action

225. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

226. The APA requires a court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §706(2)(A).

227. An agency action is arbitrary and capricious if the agency has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983). An agency action is also arbitrary and capricious if, when departing from a prior policy, an agency does not "display awareness that it *is* changing position" or does not

"show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

228. As described above, the Challenged Directives instruct defendants to take adverse action on research projects with a perceived connection to blacklisted subjects.

229. The Challenged Directives are arbitrary and capricious because they do not acknowledge—let alone provide "good reasons for"—any official change in agency "priorities." *Fox Television Stations*, 556 U.S. at 515. Indeed, upon information and belief, defendants have deliberately chosen not to expressly acknowledge any changes in agency priorities regarding research into the blacklisted topics.

230. The Challenged Directives are arbitrary and capricious for the additional reason that, in adopting and implementing them, defendants have not engaged in reasoned consideration of any individual project before terminating a grant.

231. The Challenged Directives are arbitrary and capricious for the additional reason that, in adopting and implementing them, defendants failed to consider several important aspects of the issues before them, including, at a minimum, (1) plaintiffs' reliance interests in any announced research opportunities and awarded research grants; (2) whether those projects could be adjusted, rather than terminated, to comply with defendants' new "priorities" (assuming those new "priorities" and their application to existing funding opportunities and awards were otherwise lawful); (3) whether defendants could have adopted a measure other than across-the-board delay of the grant awards process and elimination of entire categories of programs to effectuate their new "priorities" (assuming those new "priorities" and their application to existing funding opportunities and awards were otherwise lawful); and (4) as to ongoing research projects, the harm that eliminating those projects would inflict on human test subjects participating in the studies.

232. The Challenged Directives are arbitrary and capricious for the additional reason that they rely on factors which Congress has not intended defendants to consider, including considerations in conflict with the PHSA's directives in favor of diversity, equity, and inclusion.

233. Accordingly, plaintiffs are entitled to an order and judgment, and to a preliminary and permanent injunction, holding unlawful and setting aside the Challenged Directives and enjoining any action taken to enforce or implement the Challenged Directives.

Count 4—Against All Defendants
U.S. Constitution, Separation of Powers

234. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

235. Federal courts possess the power in equity to grant injunctive relief "with respect to violations of federal law by federal officials." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326-27 (2015).

236. The Constitution "grants the power of the purse to Congress, not the President." *City & County of San Francisco v. Trump*, 897 F.3d 1225, 1231 (9th Cir. 2018); *see* U.S. Const. art. I, §9, cl. 7 (Appropriations Clause); U.S. Const. art. I, §8, cl. 1 (Spending Clause). "Among Congress's most important authorities is its control of the purse." *Biden v. Nebraska*, 600 U.S. 477, 505 (2023). "The Appropriations Clause is thus a bulwark of the Constitution's separation of powers among the three branches of the National Government." *U.S. Dep't of Navy v. FLRA*, 665 F.3d 1339, 1347 (D.C. Cir. 2012) (Kavanaugh, J.). If not for the Appropriations Clause, "the executive would possess an unbounded power over the public purse of the nation." *Id*.

237. Congress also possesses exclusive power to legislate. Article I, Section 1 of the Constitution states that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and a House of Representatives." *See Clinton v.*

City of New York, 524 U.S. 417, 438 (1998) ("There is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes.").

238. The Constitution further provides that the executive must "take Care that the Laws be faithfully executed." U.S. Const. Art. II, Sec. 3; *see Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 327 (2014) ("Under our system of government, Congress makes the laws and the President . . . faithfully executes them." (brackets and quotation marks omitted)).

239. The Executive Branch violates the Take Care Clause where it declines to execute or otherwise undermines statutes enacted by Congress and signed into law or duly promulgated regulations implementing such statutes. *See In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 551 (D.C. Cir. 1999) ("[T]he President is without authority to set aside congressional legislation by executive order . . . ."); *Kendall v. United States*, 37 U.S. 524, 613 (1838) (rejecting argument that by charging the President with faithful execution of the laws, the Take Care clause "implies a power to forbid their execution"); *see also Util. Air. Reg. Grp.*, 573 U.S. at 327 (noting that the President "act[s] at time through agencies").

240. The Executive's authority vis-à-vis Congress is particularly limited where, as here, no statutes authorize the Executive's action. Congress consistently has appropriated funds to NIH's ICs to further their statutory purposes of advancing and promoting medical research and has not authorized the Executive to decline to spend vast swaths of funds. Further, Congress has provided for a procedure by which the Executive may propose to Congress to either rescind or cancel funds. *See* Congressional Budget and Impoundment Control Act of 1974, 2 U.S.C. §§682 *et seq*. That statute likewise does not permit the Executive to take unilateral action, instead requiring the President must "propose[]" any rescission to Congress (which Congress must then affirmatively approve) and may not defer funding for the policy reasons defendants explicitly

invoke here. 2 U.S.C. §§683, 684(a). Accordingly, the Executive's authority is at its "lowest ebb." *See Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 637-38 (1952) (Jackson, J., concurring).

241. Defendants' adoption, implementation, and enforcement of the Challenged Directives—including their pattern and policy of systematic delays and terminations—violates the foregoing separation-of-powers constraints. Through these actions, defendants have overridden the careful judgments of Congress by refusing to disburse duly appropriated funding.

242. Accordingly, plaintiffs are entitled to a preliminary and permanent injunction holding unlawful and setting aside, and to a declaration pursuant to 28 U.S.C. §2201 declaring unlawful, the Challenged Directives and any action taken to enforce or implement the Challenged Directives.

Count 5—Against All Defendants
U.S. Constitution, Spending Clause

243. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

244. Federal courts possess the power in equity to grant injunctive relief "with respect to violations of federal law by federal officials." *Armstrong*, 575 U.S. at 326-27.

245. The Spending Clause of the U.S. Constitution, art. I, §8, cl. 1, provides that Congress—not the Executive—"shall have Power to lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States."

246. The Spending Clause requires States to have fair notice of the terms that apply to the disbursement of funds to them. *See Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17, 25 (1981); *NFIB v. Sebelius*, 567 U.S. 519, 583-84 (2012). The funding conditions must be

set out "unambiguously." *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006). And the federal statute must be viewed "from the perspective of a state official who is engaged in the process of deciding whether the State should accept [federal statute] funds and the obligations that go with those funds." *Id.*

247. Defendants' adoption, implementation, and enforcement of the Challenged Directives—including their pattern and policy of systematic delays and retroactive terminations—has altered the terms upon which grants were obligated and disbursed to plaintiffs, contrary to Congressional authority. These alterations are coercive, retroactive, ambiguous, and unrelated to the purpose of the myriad grants affected.

248. Defendants' adoption, implementation, and enforcement of the Challenged Directives—including their pattern and policy of systematic delays and retroactive terminations—are also contrary to the principle that funding restrictions can only impose conditions that are reasonably related to the federal interest in the project and the project's objectives. *S. Dakota v. Dole*, 483 U.S. 203, 207, 208 (1987). Here, the delays and terminations are not related to the federal interest in NIH research—to support and encourage scientific research—and instead are related to policies and political factors. Indeed, the effect of these delays and terminations is to chill scientific research as they have subjected researchers and the administrators who support them to the fear that their ongoing research activities can and will be suspended based on shifting political objectives of the current Administration.

249. Accordingly, plaintiffs are entitled to a preliminary and permanent injunction holding unlawful and setting aside, and to a declaration pursuant to 28 U.S.C. §2201 declaring unlawful, the Challenged Directives and any action taken to enforce or implement the Challenged Directives.

Count 6—Against All Defendants
***Ultra Vires* Executive Action**

250. Plaintiffs incorporate by reference the foregoing paragraphs of this Amended Complaint as if set forth herein.

251. The actions challenged herein are contrary to law and outside of defendants' authority because defendants lacked statutory or constitutional authority to issue or implement the Challenged Directives and because defendants' actions are contrary to statutory requirements.

252. The Challenged Directives purport to restrict research on subjects that Congress has expressly required NIH to support. The PHSA requires NIH and its ICs to conduct research related to the health of women, racial and ethnic minorities, and sexual and gender minorities. 42 U.S.C. §§282(h), 283p, 285a-6, 285b-7a(c)(1). In declaring research related to DEI, gender identity, and transgender health off-limits, defendants' actions are contrary to congressional mandates.

253. The Challenged Directives defy statutory provisions requiring NIH to articulate its research priorities through a formal and public strategic plan. The PHSA contains detailed requirements governing this plan. The agency must develop and formalize the plan every six years. 42 U.S.C. §282(m)(1). It must consult with relevant stakeholders in doing so. *Id.* §282(m)(4). The plan must contain a host of information, including "strategic research priorities and objectives," "priorities and objectives to advance the treatment, cure, and prevention of health conditions," and "near-, mid-, and long-term scientific needs." *Id.* §282(m)(2)(A). And the agency must submit the plan to Congress and post it on its website. *Id.* §282(m)(1). Defendants' promulgation and implementation of the Challenged Directives—which have effected large-scale changes in agencies priorities without the development and consultation called by for the creation of a new Strategic Plan—are contrary to this congressionally mandated process.

254. The adoption and enforcement of the Challenged Directives exceed defendants' statutory authority because they conflict with duly enacted congressional appropriations. Congress appropriated funds to NIH's ICs so that those funds would be spent in accordance with the statutory purposes and public priorities just discussed. Congress allocated certain sums of money to NIH so that the agency could use those sums during the fiscal year. In implementing the Challenged Directives, defendants have interrupted the flow of funding to existing projects and precluded the prompt awarding of new grants—with a dwindling opportunity to reallocate funds before they are no longer available at the end of the fiscal year. These actions are contrary to the purpose for which the funds were appropriated and Congress's longstanding and well-established framework of NIH funding. *See* 31 U.S.C. §1301(a) (funds "shall be applied only to the objects for which the appropriations were made except as otherwise provided by law"); *Gen. Land Office v. Biden*, 722 F. Supp. 3d 710, 732 (S.D. Tex. 2024) ("While agencies are afforded discretion for certain lump-sum appropriations decisions, their actions still must remain within the bounds of the statute." (citation omitted)); *California v. Trump*, 379 F. Supp. 3d 928, 953 (N.D. Cal. 2019), *aff'd*, 963 F.3d 926 (9th Cir. 2020) (judicial review is available under the APA where plaintiffs allege that funds are being used "in a statutorily *impermissible* manner"); *Lincoln v. Vigil*, 508 U.S. 182, 193 (1993) ("[A]n agency is not free simply to disregard statutory responsibilities: Congress may always circumscribe agency discretion to allocate resources by putting restrictions in the operative statutes . . . .")).

255. Defendants cannot take any action that exceeds the scope of their constitutional and statutory authority.

256. Federal courts possess the power in equity to grant injunctive relief "with respect to violations of federal law by federal officials." *Armstrong*, 575 U.S. at 326-27. Indeed, the

Supreme Court has repeatedly allowed equitable relief against federal officials who act "beyond th[e] limitations" imposed by federal statute. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

257. Accordingly, plaintiffs are entitled to preliminary and permanent injunctive relief barring the actions challenged herein. Pursuant to 28 U.S.C. §2201, plaintiffs are also entitled to a declaration that the actions challenged herein are contrary to law and outside of defendants' authority.

Count 7—Against All Defendants
Administrative Procedure Act, 5 U.S.C. §706(1):
Unlawful Withholding and/or Unreasonable Delay of Agency Action

258. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

259. The APA authorizes a court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. §706(1). Relief is warranted under this provision where an agency completely fails to take, or unreasonably delays in taking, "a discrete agency action that it is required to take." *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (emphasis omitted); *see id.* at 63 n. 1.

260. The APA provides that, "within a reasonable time, each agency *shall* proceed to conclude a matter presented to it." 5 U.S.C. §555(b) (emphasis added).

261. The PHSA provides that applications for NIH research grants shall undergo "technical and scientific peer review" by a study section, and that a favorable review is a prerequisite to a final award of any grant. 42 U.S.C. §§284(b)(2)(B), 289a(a). The PHSA further states that each NIH institute's advisory council "*shall* meet . . . at least three times each fiscal year," *id.* §284(e) (emphasis added), and that it "*shall* advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute" on areas within the council's

jurisdiction, *id.* §284(a)(1) (emphasis added). The PHSA also provides that sign-off from an advisory council is a prerequisite to a final award of any grant in excess of $50,000. *Id.* §284(b)(2); *see id.* §284a(a)(3)(A)(ii).

262. Under NIH regulations, "[a]ll applications" for NIH grants "*shall* be evaluated by the [HHS] Secretary [or his designee] through such officers and employees and such experts or consultants engaged for this purpose as the Secretary determines are specially qualified in the areas of research involved in the project, including review by an appropriate National Advisory Council." 42 C.F.R. §52.5(a) (emphasis added); *see also id.* §52a.5 ("NIH grants may be awarded generally only after approval recommendations from both appropriate scientific peer review groups and national advisory councils or boards."). The regulations further provide for the creation of study groups and reiterate that "no awarding official shall award a grant . . . unless the application has been reviewed by a peer review group . . . and the group has made recommendations concerning the scientific merit of that application." *Id.* §52h.7; *see generally id.*, pt. 52h. Moreover, the regulations provide that, "subject to approvals, recommendations or consultations by the appropriate National Advisory Council or other body as may be required by law, the Secretary *will* (1) approve, (2) defer because of either lack of funds or a need for further evaluation, or (3) disapprove support of the proposed project in whole or in part." *Id.* §52.5(b) (emphasis added).

263. For the foregoing reasons, the following are discrete agency actions that NIH is required to take: (a) the activities of NIH's advisory councils, including the holding of council meetings, the review of pending grant applications by the relevant council, and the making of a final recommendation on each application by the relevant council, (b) the activities of NIH's study sections, including the holding of section meetings, the review of pending grant applications by

the relevant study section, and the making of a final recommendation on each application by the relevant study section—are likewise discrete agency actions that NIH is required to take, and (c) the prompt review and issuance of a final decision on NIH grant applications and renewal requests.

264. As discussed, in implementing the Challenged Directives, defendants have cancelled and/or substantially delayed the above-described required activities of NIH's advisory councils and study sections—a significant and unprecedented departure from the NIH's published review process and the agency's past practice.

265. As discussed, in implementing the Challenged Directives, defendants have refused to process the Delayed Applications, including those of the Delayed Applications that have already received a "fundable" score from the relevant study section and/or a favorable recommendation from the relevant advisory council.

266. As discussed, in implementing the Challenged Directives, defendants have failed to process the Delayed Renewals even though they meet the requirement for renewal.

267. The above-described meeting cancellations and delays in application review constitute unlawful withholding and/or unreasonable delay of agency action within the meaning of §706(1). *See, e.g.*, *Rezaii v. Kennedy*, No. 1:24-cv-10838, 2025 WL 750215, at *5 (D. Mass. Feb. 24, 2025) (holding that a plaintiff had pleaded unreasonable delay where, among other things, the agency's delay in processing plaintiff's application was "at the outer edge of HHS's typical time for processing"); *Raouf v. U.S. Dep't of State*, 702 F. Supp. 3d 19, 33 (D.N.H. 2023) (finding that a plaintiff had pleaded unreasonable delay where she alleged that the "delay [was] attributable to . . . an *ultra vires* internal policy for intentionally delaying issuance of visas").

268. As discussed above, the above-described meeting cancellations and delays in application review have caused, are causing, and imminently threaten to cause direct, concrete, and irreparable harm to plaintiffs.

269. For the foregoing reasons, plaintiffs are entitled to an order, and to a preliminary and permanent injunction, compelling defendants to undertake: (a) the required unreasonably delayed and unlawfully withheld activities of NIH's advisory councils and study sections, and (b) the required unreasonably delayed and unlawfully withheld prompt review and issuance of a final decision on the Delayed Applications and Delayed Renewals.

Count 8—All Defendants
Declaratory Judgment

270. Plaintiffs reallege and incorporate by reference the allegations contained in each of the preceding paragraphs as if fully set forth herein.

271. An actual and substantial controversy exists between plaintiffs and defendants about whether 2 C.F.R. §200.340(a)(2) (2020) and 2 C.F.R. §200.340(a)(4) (2024) permit NIH to terminate awarded grants on the grounds that NIH identified "agency priorities" after the award of the grant which the grant does not effectuate.

272. This action is presently justiciable because defendants have asserted: (a) that §200.340 permits NIH, as a matter of law, to terminate awarded grants on the grounds that NIH's "agency priorities" have changed since the award of the grant; and (b) that this interpretation of §200.340 permits NIH to terminate plaintiffs' awarded grants on the grounds that they relate to research areas that are no longer "agency priorities."

273. Plaintiffs assert that while 2 C.F.R. §200.340(a)(2) (2020) and 2 C.F.R. §200.340(a)(4) (2024) permit the termination of a federal award if the award no longer effectuates agency priorities identified as of the time of the federal award, these provisions do not

independently permit or authorize such termination based on agency priorities identified after the time of the Federal award.

274. Declaratory relief will clarify the rights and obligations of the parties and, therefore, pursuant to 28 U.S.C. §2201, is appropriate to resolve this controversy.

PRAYER FOR RELIEF

Wherefore, plaintiffs pray that the Court:

I. Enter an order pursuant to 5 U.S.C. §706(2) holding unlawful and setting aside the Challenged Directives, and any action taken to enforce or implement the Challenged Directives, on the ground that they are (a) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, and/or otherwise not in accordance with governing statutes; (b) not in accordance with governing regulations; and (c) arbitrary and capricious;

II. Declare pursuant to 28 U.S.C. §2201 that the Challenged Directives, and any action taken to enforce or implement the Challenged Directives, are unconstitutional because they violate (a) the separation of powers and (b) the Spending Clause;

III. Enter a preliminary and permanent injunction barring defendants from carrying out the Challenged Directives and any actions to enforce or implement the Challenged Directives, including, without limitation, by directing defendants to: (a) reissue Notices of Funding Opportunities (NOFOs) withdrawn based on the Challenged Directives and to refrain from withdrawing NOFOs based on the Challenged Directives; (b) refrain from denying grant applications or renewal applications based on the Challenged Directives; (c) release reimbursements and other funding for awards that defendants have refused to pay based on the Challenged Directives; (d) rescind the termination of the Terminated Grants and refrain from eliminating funding for awards based on the Challenged Directives; and (e) promptly reschedule

and conduct all necessary steps in the review and disposition of plaintiffs' grant applications, including the Delayed Applications and Delayed Renewals;

IV. Enter an order pursuant to 5 U.S.C. §706(1) compelling defendants to undertake: (a) the required unreasonably delayed and unlawfully withheld activities of NIH's advisory councils and study sections, and (b) the required unreasonably delayed and unlawfully withheld prompt review and issuance of a final decision on the Delayed Applications and Delayed Renewals;

V. Declare pursuant to 28 U.S.C. §2201 that 2 C.F.R. §200.340(a)(2) (2020) and 2 C.F.R. §200.340(a)(4) (2024) do not independently permit or authorize termination of awarded grants based on agency priorities identified after the time of the Federal award; and

VI. Award such additional relief as the interests of justice may require.

April 14, 2025

Respectfully submitted.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Civil Action No. 1:25-cv-10787-WGY

NOTICE OF APPEAL

Pursuant to Rule 4(a)(1) of the Federal Rules of Appellate Procedure, all Defendants[1] hereby appeal to the United States Court of Appeals for the First Circuit from the order and partial final judgment entered in this case on June 23, 2025, Doc No. 138, as well as from all other interlocutory orders merged into that order and judgment.

Respectfully submitted,

BRETT A. SHUMATE
Assistant Attorney General

LEAH B. FOLEY
United States Attorney

KIRK T. MANHARDT
Director

MICHAEL J. QUINN
Senior Litigation Counsel

Dated: June 23, 2025

/s/ Anuj Khetarpal

[1] National Institutes of Health; Jay Bhattacharya, in his official capacity as Director of the National Institutes of Health, United States Department of Health and Human Services, and Robert F. Kennedy, Jr., in his official capacity as Secretary of the United States Department of Health and Human Services.

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Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: June 23, 2025

/s/ Anuj Khetarpal
Anuj Khetarpal

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 1:25-cv-10814-WGY

NOTICE OF APPEAL

Pursuant to Rule 4(a)(1) of the Federal Rules of Appellate Procedure, all defendants[1] hereby appeal to the United States Court of Appeals for the First Circuit from the order and partial final judgment entered in this case on June 23, 2025, Doc No. 151, as well as from all other interlocutory orders merged into that order and judgment.

[1] Defendants Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services; United States Department of Health and Human Services; Jayanta Bhattacharya, in his official capacity as the Director of the National Institutes of Health; National Institutes of Health; National Cancer Institute; National Eye Institute; National Heart, Lung, and Blood Institute; National Human Genome Research Institute; National Institute on Aging; National Institute on Alcohol Abuse and Alcoholism; National Institute of Allergy and Infectious Diseases; National Institute of Arthritis and Musculoskeletal and Skin Diseases; National Institute of Biomedical Imaging and Bioengineering; Eunice Kennedy Shriver National Institute of Child Health and Human Development; National Institute on Deafness and Other Communication Disorders; National Institute of Dental and Craniofacial Research; National Institute of Diabetes and Digestive and Kidney Diseases; National Institute on Drug Abuse; National Institute of Environmental Health Sciences; National Institute of General Medical Sciences; National Institute of Mental Health; National Institute on Minority Health and Health Disparities; National Institute of Neurological Disorders and Stroke; National Institute of Nursing Research; National Library of Medicine; National Center for Advancing Translational Sciences; John E. Fogarty International Center for Advanced Study in the Health Sciences; National Center for Complementary and Integrative Health; and Center for Scientific Review.

Respectfully submitted,

BRETT A. SHUMATE
Assistant Attorney General

LEAH B. FOLEY
United States Attorney

KIRK T. MANHARDT
Director

MICHAEL J. QUINN
Senior Litigation Counsel

Dated: June 23, 2025

/s/ Thomas W. Ports, Jr.

THOMAS W. PORTS, Jr. (Va. Bar No. 84321)
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Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: June 23, 2025

/s/ Thomas W. Ports, Jr.
Thomas W. Ports, Jr.

National Institutes of Health
Office of Extramural Research

Date: February 12, 2025

To: Institute and Center Chief Grants Management Officers (IC CGMOs)

From: Michael S. Lauer, MD Michael S. Lauer -S Digitally signed by Michael S. Lauer -S Date: 2025.02.12 09:26:33 -05'00'
Deputy Director for Extramural Research, National Institutes of Health (NIH)

Michelle G. Bulls
NIH Chief Grants Management Officer

Subject: NIH Review of Agency Priorities Based on the New Administration's Goals

NIH is in the process of reevaluating the agency's priorities based on the goals of the new administration. NIH will effectuate the administration's goals over time, but given recent court orders, this cannot be a factor in IC funding decisions at this time. In consultation with NIH leadership and with the Office of General Counsel (OGC), we recognize that NIH programs fall under recently issued Temporary Restraining Orders (*New York et al. v. U.S. Office of Management and Budget* and *Commonwealth of Massachusetts et al. v. National Institutes of Health et al* see attached). Therefore, with this memo, IC CGMOs are authorized, along with their respective grants management staff, to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements (previously cleared through Office of Extramural Research) grants. Until further notice, as awards are issued, ICs must follow their existing FY25 IC funding policies and use the previously approved negotiated indirect cost rates. Additional details on future funding actions related to the agency's goals will be provided under a separate memo.

Attachments

1. Temporary Restraining Order, *New York et al. v. U.S. Office of Management and Budget* (Jan. 31, 2025)

2. Court Order Questions – HHS OGC Responses (February 4, 2025)

3. Temporary Restraining Order, *Commonwealth of Massachusetts et al. v. National Institutes of Health et al.,* (February 10, 2025)

4. Order Enforcing TRO, *New York et al. v. U.S. Office of Management and Budget* (February 10, 2025)

5. Office of General Counsel Note, *New York et al. v. U.S. Office of Management and Budget* (February 10, 2025)

National Institutes of Health
Office of Extramural Research

Date: February 13, 2025

To: Institute and Center Chief Grants Management Officers (IC CGMOs)

From: Michael S. Lauer, MD
Deputy Director for Extramural Research, National Institutes of Health (NIH)

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S Date: 2025.02.13 15:06:52 -05'00'

Michelle G. Bulls
NIH Chief Grants Management Officer

Subject: Supplemental Guidance to Memo Entitled- NIH Review of Agency Priorities Based on the New Administration's Goals

The Office of Extramural Research is issuing supplemental guidance to the memo, dated February 12, 2025, to Institute and Center (IC) Chief Grants Management Officers (CGMOs) and their respective staff to issue hard funding restrictions on awards and within the Payment Management System (PMS)/Program Support Center (PSC) on awards where the program promotes or takes part in diversity, equity, and includsion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or any other protected characteristics. The restriction requirement applies to new and continuation awards made on or after February 14, 2025. If the sole purpose of the grant, cooperative agreement, other transaction award (including modifications), or supplement supports DEI activities, then the award must be fully restricted. The restrictions will remain in place until the agency conducts an internal review for payment integrity. Such review shall include, but not be limited to a review for fraud, waste, abuse, of all grants, cooperative agreements, and Other Transactions that determines the funding of the activities/program are in the best interest of the government and consistent with current policy priorities.

Attachments

1. Memo NIH Review of Agency Priorities Based on the New Administration's Goals, February 12, 2025

2. UPDATE - Temporary Restraining Order in State of New York et al. v. Trump et al., 1:25-cv-00039 (D.R.I.), February 12, 2025

3. Secretarial Directive on DEI Related Funding, February 10, 2025

Directive on NIH Priorities

Agency: National Institutes of Health

Office of the Director

Action: Directive

FOR FURTHER INFORMATION CONTACT:

National Institutes of Health

Office of the Director

EFFECTIVE DATE: February 21, 2025

Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards

The National Institutes of Health (NIH) is the largest public funder of biomedical and behavioral research in the world. The public trusts NIH with substantial funds to foster creative discoveries that will improve health and prevent disease in this Country. Accordingly, NIH is committed to promoting only the highest level of scientific integrity, public accountability, and social responsibility in the programs it funds. And NIH promises to prioritize the funding of projects that will generate a high return on the public's investment, so that taxpayer dollars are not going to waste. Every dollar should be used to make Americans live longer, healthier lives.

This mission requires NIH to ensure that it is not supporting low-value and off-mission research programs, including but not limited to studies based on diversity, equity, and inclusion (DEI) and gender identity. While this description of NIH's mission is consistent with recent Executive Orders issued by the President, I issue this directive based on my expertise and experience; consistent with NIH's own obligation to pursue effective, fiscally prudent research; and pursuant to NIH authorities that exist independently of, and precede, those Executive Orders.

Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, DEI studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Likewise, research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs either.

For these reasons and pursu ies, 42 U.S.C. § 282(b) and 45 C.F.R. Part 75 (45 C.F.R. §§ 75.20 : Director of NIH hereby directs:

NIH personnel shall of all contract solicitations and notices of funding o nding Type 1 and Type 2 awards; existing awards; coc her transactions. Such review shall be aimed at en , cooperative agreements, and other transactions d lue and off-mission research activities or projects r identity research activities and programs. NIH pers ants, contracts, cooperative agreements, and oth . fraud, abuse, and duplication, and are being imple ral law.

This Directive shall be impl I personnel, including but not limited to those in the Office of Extramural Research, Office of Intramural Research, and the Division of Program Coordination, Planning, and Strategic Initiatives. Grants, contracts, cooperative agreements, and other transactions deemed inconsistent with NIH's mission may, where permitted by applicable law, be subject to funding restrictions, terminated or partially terminated, paused, and/or not continued or renewed, in compliance with all procedural requirements.

Notwithstanding this Directive, and consistent with any court orders that may apply, no open award disbursements may be paused in reliance upon Office of Management and Budget Memorandum M-25-13 or any Executive Order underlying that Memorandum. Previous instructions ordering the immediate release of such funds remain in effect. Also, consistent with any court orders that may apply, this Directive does not instruct personnel to condition or withhold federal funding pursuant to Section 4 of Executive Order 14,187 (Protecting Children from Chemical and Surgical Mutilation) based on the fact that a healthcare entity or health professional provides care or treatment.

Dated: February 21, 2025

of NIH

[1] To be clear, these citations are illustrative, not exhaustive. Further explanation of the range of statutory and regulatory authorities that support actions taken pursuant to this Directive will be issued as appropriate.

From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: Bulls, Michelle (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Sass-Hurst, Brian (NIH/OD) [E]
Subject: DEI Staff Guidance - Final - March 4 2025
Date: Tuesday, March 04, 2025 11:02:00 AM
Attachments: DEI Staff Guidance - Final 3.4.25.pdf

Good morning,
Attached is staff guidance that includes the DEI term along with details on when the term must be applied. Let's plan to talk through this guidance and note Dr. Memoli has **approved** the DEI term for immediate use. I have also added the process for terminating awards based in DEI as provided to us by HHS. I will follow up with a few of you to pull out the details needed to address terminations that were made yesterday—just to pull the information out and to address specific questions. Finishing up meetings and then, I will that information out to all that were impacted by yesterday's termination list provided to us by HHS/ASA.
Thanks,
Michelle

Staff Guidance –Award Assessments for Alignment with Agency Priorities - March 2025

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities. To avoid issuing awards, in error, that support DEI activities ICs must take care to completely excise all DEI activities using the following categories.

Category 1: The sole purpose of the project is DEI related (e.g., diversity supplements or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that was unpublished as outlined above.

- Action: ICs must not issue the award.

Category 2: Project partially supports DEI activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope) this means DEI activities are ancillary to the purpose of the project. In some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the DEI Restriction Term of Award in Section IV of the Notice of Award, no exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Action 1: Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file.
- Action 2: Once the IC and the applicant/recipient have reached an agreement, issue the award and include the DEI Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.
  - **Note:** If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the DEI related activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Appendix 2.

Category 3: Project does not support DEI activities, but may contain language related to DEI (e.g., statement regarding institutional commitment to diversity in the 'Facilities & Other Resources' attachment and terminology related to structural racism—this is not all-inclusive).

- Action 1: Funding IC must request an updated application/RPPR with the DEI language removed.
- Action 2: Once the language has been removed, the IC may proceed with issuing the award.

Category 4: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

> **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

Appendix 2 – Guidance for staff to use when terminating awards identified by HHS or the IC.

- Issue a revised NOA.
    - Change the budget and project period end dates to match the date of the termination letter.
    - Check PMS, determine amount of funds remaining, and deobligate the amount reflected in PMS when revising the NOA. Note: This applies to Multi-Year Funded Awards, as well. Work with FFR-C if you have questions regarding deobligating funds to avoid placing the recipient in debt collection.
    - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and the HHS requests a termination, the project must be terminated
    - Use the following termination term: This award related to [select the appropriate example relevant to your project by choosing one of the highlighted examples DEI, China, or Transgender issues] no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award is terminated. [Refer to Appendix 3 for language provided to NIH by HHS.] Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR)) within 120 days of the end of this grant to avoid unilateral closeout.
    - Insert restriction language that allows for the recipients to use a portion of funds to support the health and safety of patients and orderly closeout of the project.
        - Sample language for use: "Funds in the amount of $xxxxxxx [insert $ amount total cost] may be used to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered."
- Appeals language must be used (prior to October 1, 2025):
    - NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This letter represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli.

      Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be postmarked no later than 30 days after the postmarked date of this notice.
- Termination actions taken based on agency priorities do not require appeals language because the action was not based on administrative nor programmatic noncompliance

Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Appendix 4 – Approved Term – Use for all Category 2 awards, i.e., renegotiated aims and associated budgets. Approval embedded below. ICs should use this term in the IC specific award conditions

Term and Condition of Award

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including Diversity Equity and Inclusion (DEI) research or DEI-related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes DEI or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

From: Memoli, Matthew (NIH/OD) [E]
To: Bundesen, Liza (NIH/OD) [E]
Cc: Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject: Re: Clean Version of DEI Restriction Term - Final
Date: Friday, February 28, 2025 2:54:19 PM

---

approved

Matt

Get Outlook for iOS

From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs, Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
Liza

INTERNAL: NOT FOR DISTRIBUTION OUTSIDE THE GOVERNMENT

NIH Grants Management Staff Guidance –Award Assessments for Alignment with Agency Priorities - March 2025

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities. To avoid issuing awards, in error, that support DEI activities ICs must take care to completely excise all DEI activities using the following categories.

Category 1: The sole purpose of the project is DEI related (e.g., diversity supplements or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that was unpublished as outlined above.

- Action: ICs must not issue the award.

Category 2: Project partially supports DEI activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope) this means DEI activities are ancillary to the purpose of the project. In some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the DEI Restriction Term of Award in Section IV of the Notice of Award, no exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Action 1: Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file.
- Action 2: Once the IC and the applicant/recipient have reached an agreement, issue the award and include the DEI Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.
  - **Note:** If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the DEI related activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Appendix 2.

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INTERNAL: NOT FOR DISTRIBUTION OUTSIDE THE GOVERNMENT

Category 3: Project does not support DEI activities, but may contain language related to DEI (e.g., statement regarding institutional commitment to diversity in the 'Facilities & Other Resources' attachment and terminology related to structural racism—this is not all-inclusive).

- Action 1: Funding IC must request an updated application/RPPR with the DEI language removed.
- Action 2: Once the language has been removed, the IC may proceed with issuing the award.

Category 4: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

> **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

INTERNAL: NOT FOR DISTRIBUTION OUTSIDE THE GOVERNMENT

Appendix 2 – Guidance for staff to use when terminating awards identified by HHS or the IC.

- Issue a revised NOA.
    - Change the budget and project period end dates to match the date of the termination letter.
    - Check PMS, determine amount of funds remaining, and deobligate the amount reflected in PMS. It is very important to notify the FFR-C: OPERAFFRInquiries@od.nih.gov on all IC deoblgiations prior to reducing the award, so the FFR-C can deobligate any remaining 'cents' to avoid challenges with financial closeout.
    - Note: This applies to Multi-Year Funded Awards, as well. Please contact the FFR-C if you have questions regarding deobligating funds to avoid placing the recipient in debt collection.
    - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and the HHS requests a termination, the project must be terminated
    - Use the following termination term: This award related to [select the appropriate example relevant to your project by choosing one of the highlighted examples DEI, China, or Transgender issues] no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award is terminated. [Refer to Appendix 3 for language provided to NIH by HHS.] Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant to avoid unilateral closeout.
    - Insert restriction language that allows for the recipients to use a portion of funds to support the health and safety of patients and orderly closeout of the project.
        - Sample language for use: "Funds in the amount of $xxxxxxx [insert $ amount total cost] may be used to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered."
- Appeals language must be used (prior to October 1, 2025):
    - NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This letter represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli.

      Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally,

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INTERNAL: NOT FOR DISTRIBUTION OUTSIDE THE GOVERNMENT

the appeal must be signed by the institutional official authorized to sign award applications and must be postmarked no later than 30 days after the postmarked date of this notice.

- Termination actions taken based on agency priorities do not require appeals language because the action was not based on administrative nor programmatic noncompliance

Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Appendix 4 – Approved Term – Use for all Category 2 awards, i.e., renegotiated aims and associated budgets. Approval embedded below. ICs should use this term in the IC specific award conditions

Term and Condition of Award

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including Diversity Equity and Inclusion (DEI) research or DEI-related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review

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includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes DEI or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

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From: Memoli, Matthew (NIH/OD) [E]
To: Bundesen, Liza (NIH/OD) [E]
Cc: Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject: Re: Clean Version of DEI Restriction Term - Final
Date: Friday, February 28, 2025 2:54:19 PM

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approved

Matt

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From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs, Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
Liza

From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: Bulls, Michelle (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Sass-Hurst, Brian (NIH/OD) [E]
Subject: DEI Staff Guidance - Final - March 4 2025
Date: Tuesday, March 04, 2025 11:02:00 AM
Attachments: DEI Staff Guidance - Final 3.4.25.pdf

Good morning,
Attached is staff guidance that includes the DEI term along with details on when the term must be applied. Let's plan to talk through this guidance and note Dr. Memoli has **approved** the DEI term for immediate use. I have also added the process for terminating awards based in DEI as provided to us by HHS. I will follow up with a few of you to pull out the details needed to address terminations that were made yesterday—just to pull the information out and to address specific questions. Finishing up meetings and then, I will that information out to all that were impacted by yesterday's termination list provided to us by HHS/ASA.
Thanks,
Michelle

Staff Guidance –Award Assessments for Alignment with Agency Priorities - March 2025

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities. To avoid issuing awards, in error, that support DEI activities ICs must take care to completely excise all DEI activities using the following categories.

Category 1: The sole purpose of the project is DEI related (e.g., diversity supplements or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that was unpublished as outlined above.

- Action: ICs must not issue the award.

Category 2: Project partially supports DEI activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope) this means DEI activities are ancillary to the purpose of the project. In some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the DEI Restriction Term of Award in Section IV of the Notice of Award, no exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Action 1: Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file.
- Action 2: Once the IC and the applicant/recipient have reached an agreement, issue the award and include the DEI Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.
  - **Note:** If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the DEI related activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Appendix 2.

Category 3: Project does not support DEI activities, but may contain language related to DEI (e.g., statement regarding institutional commitment to diversity in the 'Facilities & Other Resources' attachment and terminology related to structural racism—this is not all-inclusive).

- Action 1: Funding IC must request an updated application/RPPR with the DEI language removed.
- Action 2: Once the language has been removed, the IC may proceed with issuing the award.

Category 4: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

> **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

Appendix 2 – Guidance for staff to use when terminating awards identified by HHS or the IC.

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    - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and the HHS requests a termination, the project must be terminated
    - Use the following termination term: This award related to [select the appropriate example relevant to your project by choosing one of the highlighted examples DEI, China, or Transgender issues] no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award is terminated. [Refer to Appendix 3 for language provided to NIH by HHS.] Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR)) within 120 days of the end of this grant to avoid unilateral closeout.
    - Insert restriction language that allows for the recipients to use a portion of funds to support the health and safety of patients and orderly closeout of the project.
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      Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be postmarked no later than 30 days after the postmarked date of this notice.
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Term and Condition of Award

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This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes DEI or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

From: Memoli, Matthew (NIH/OD) [E]
To: Bundesen, Liza (NIH/OD) [E]
Cc: Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject: Re: Clean Version of DEI Restriction Term - Final
Date: Friday, February 28, 2025 2:54:19 PM

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approved

Matt

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From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
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Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
Liza

Staff Guidance –Award Assessments for Alignment with Agency Priorities - March 2025

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities. To avoid issuing awards, in error, that support DEI activities ICs must take care to completely excise all DEI activities using the following categories.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

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February 10, 2025

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Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

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- Termination actions taken based on agency priorities do not require appeals language because the action was not based on administrative nor programmatic noncompliance

Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Appendix 4 – Approved Term – Use for all Category 2 awards, i.e., renegotiated aims and associated budgets. Approval embedded below. ICs should use this term in the IC specific award conditions

Term and Condition of Award

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including Diversity Equity and Inclusion (DEI) research or DEI-related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes DEI or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

From: Memoli, Matthew (NIH/OD) [E]
To: Bundesen, Liza (NIH/OD) [E]
Cc: Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject: Re: Clean Version of DEI Restriction Term - Final
Date: Friday, February 28, 2025 2:54:19 PM

---

approved

Matt

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From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs, Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
Liza

Staff Guidance –Award Assessments for Alignment with Agency Priorities - March 2025

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities. To avoid issuing awards, in error, that support DEI activities ICs must take care to completely excise all DEI activities using the following categories.

Category 1: The sole purpose of the project is DEI related (e.g., diversity supplements or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that was unpublished as outlined above.

- Action: ICs must not issue the award.

Category 2: Project partially supports DEI activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope) this means DEI activities are ancillary to the purpose of the project. In some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the DEI Restriction Term of Award in Section IV of the Notice of Award, no exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Action 1: Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file.
- Action 2: Once the IC and the applicant/recipient have reached an agreement, issue the award and include the DEI Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.
  - **Note:** If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the DEI related activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Appendix 2.

Category 3: Project does not support DEI activities, but may contain language related to DEI (e.g., statement regarding institutional commitment to diversity in the 'Facilities & Other Resources' attachment and terminology related to structural racism—this is not all-inclusive).

- Action 1: Funding IC must request an updated application/RPPR with the DEI language removed.
- Action 2: Once the language has been removed, the IC may proceed with issuing the award.

Category 4: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

> **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

Appendix 2 – Guidance for staff to use when terminating awards identified by HHS or the IC.

- Issue a revised NOA.
    - Change the budget and project period end dates to match the date of the termination letter.
    - Check PMS, determine amount of funds remaining, and deobligate the amount reflected in PMS when revising the NOA. Note: This applies to Multi-Year Funded Awards, as well. Work with FFR-C if you have questions regarding deobligating funds to avoid placing the recipient in debt collection.
    - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and the HHS requests a termination, the project must be terminated
    - Use the following termination term: This award related to [select the appropriate example relevant to your project by choosing one of the highlighted examples DEI, China, or Transgender issues] no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award is terminated. [Refer to Appendix 3 for language provided to NIH by HHS.] Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR)) within 120 days of the end of this grant to avoid unilateral closeout.
    - Insert restriction language that allows for the recipients to use a portion of funds to support the health and safety of patients and orderly closeout of the project.
        - Sample language for use: "Funds in the amount of $xxxxxxx [insert $ amount total cost] may be used to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered."
- Appeals language must be used (prior to October 1, 2025):
    - NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This letter represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli.

      Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be postmarked no later than 30 days after the postmarked date of this notice.
- Termination actions taken based on agency priorities do not require appeals language because the action was not based on administrative nor programmatic noncompliance

Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Appendix 4 – Approved Term – Use for all Category 2 awards, i.e., renegotiated aims and associated budgets. Approval embedded below. ICs should use this term in the IC specific award conditions

Term and Condition of Award

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including Diversity Equity and Inclusion (DEI) research or DEI-related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes DEI or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

From:	Memoli, Matthew (NIH/OD) [E]
To:	Bundesen, Liza (NIH/OD) [E]
Cc:	Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject:	Re: Clean Version of DEI Restriction Term - Final
Date:	Friday, February 28, 2025 2:54:19 PM

approved

Matt

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From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs, Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
Liza

From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: Bulls, Michelle (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]
Subject: Award Revision Guidance and List of Terminated Grants via letter on 3/12
Date: Thursday, March 13, 2025 4:03:00 PM
Attachments: Termination Categories 3.13.25.docx
Terminated Grants 3-12_no subprojects.xlsx

Chiefs,

Attached are two items: 1) updated categories for you to use when issuing NOAs to officially terminate the awards where letters were issued, and 2) the list of termination letters that were issued yesterday. Please revise your NOAs related to the attached list by next **Wednesday, March 13, 2025, cob**. It is extremely important that issue the revised awards timely. If there are delays, please let me know and we can try to help somehow/some way. I appreciate you all.

Please save this guidance until we can clear the updated staff guidance, and you will need this to issue revised awards. Note: If your IC is not listed on the attached spreadsheet – no action is required, at this time.

Guidance for IC staff to use when terminating awards identified by HHS or the IC due to DEI or other agency priorities.

- Issue a revised NOA.
    1. Change the budget and project period end dates to match the date of the termination letter.
    2. OPERA will place a hard funds restriction on all documents within the excel spreadsheet. Do not deobigate any funds when you issue the revised award to terminate the projects. If there are no animals and humans, FFR-C will deobligate the awards after the Final FFRs are submitted. No deoblgiation actions required from the ICs.
    3. Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated.
    4. Termination Term to be used **DELETE THE OLD TERM RELATED TO DOLLAR AMOUNTS FOR HARD FUNDS RESTRICTIONS – IT IS NO LONGER APPLICABLE**.

        It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.
        NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a

copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Thanks,
Michelle

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities- March 2025

Issue Date: March 25, 2025

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI, gender identity or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICs must take care to completely excise all non-priority activities using the following categories.

ICs should review the current application/RPPR under consideration, only. ICs should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted. Categories 1-3 are IC determinations not those ordered by HHS.

Category 1: The sole purpose of the project is related to an area that is no longer an NIH/HHS priority/authority (e.g., diversity supplements, diversity fellowships, or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority. This applies to all projects, including phased awards, etc.

- **Action:** ICs must not issue the award (competing or non-competing).
- For ongoing projects where NIH will not issue the next Type 5 (IC determination not HHS list), the IC must:
  - Issue a revised award to remove all outyears.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (access limited to CGMOs).
  - Include the following term in the revised NOA:

    Term of Award:

    It is the policy of NIH not to prioritize research programs related to [insert category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project, and remaining funds will be deobligated. Funds used to support any

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other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

- Check PMS to determine amount of funds remaining, and if funds are available request a hard funds restriction of all funds except $1 in PMS.

- **No cost extension requests:** For second and third NCE's, ICs must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS priority/authority and, if so, issue an award to end the grant project (use disapproved extension term below). If the non-NIH/HHS priority/authority research activities are ancillary to the project, approve the extension (use approved extension term below). Reminder – even if a grant project is in an NCE, IC staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly closeout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

  - ICs may use the following term of award when approving/disapproving NCEs:
    - **Term of Award (approved extension):** The no-cost extension has been approved for this project to support orderly closeout of the project, only. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs. Any funds used to support such activities will result in a disallowance of costs, and funds will be recovered.
    - **Term of Award (disapproved extension**): The no cost extension request for this project has been denied. Please proceed with orderly closeout of the project. NIH grant funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs.

Category 2: Project partially supports non-NIH/HHS priority/authority activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope). This means the non-NIH/HHS priority/authority activities are

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ancillary to the purpose of the project, in some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the Restriction Term of Award in Section IV of the Notice of Award. No exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file. The recipient/awardee cannot rebudget these funds, they must be recovered by the IC. OPERA is consulting with eRA on options to collect these application updates in a structured format.
  - Sample language for requesting application updates from the AOR: It is the policy of NIH not to prioritize [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa.] [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section [XXXX] of your application. Please work with the PD/PI to update the application sections and adjust the budget as appropriate to remove all [insert appropriate activity] activities and submit these updates to the Program Official and Grants Management Specialist for review and approval.
- **Action 2:** Once the IC and the applicant/recipient have reached an agreement, issue the award and include the following Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.

  Term of Award (Approved 2/28/2025 – Refer to Appendix 4 for the approval from Dr. Memoli):

  NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa, etc.] research or related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

  This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes

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[select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa., etc.] or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

- **Unable to remove activities that are not an NIH/HHS priority/authority:** If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Category 4.
- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICs must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the DEI Term and Condition of Award in Section IV of the NOA of the parent grant. The IC must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the IC must revise the prior year award to remove references to those outyear commitments.
- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific topics that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the IC must work with the applicant/recipient to open the conference up to all populations. If a negotiation to broaden the target audience is not feasible, or the conference is no longer viable, then the IC must terminate the award following the process in Category 4.
- **Diversity Reports (e.g., Ts, R25, K12, and any others):** NIH is modifying the application instructions and RPPR instructions to remove requirements for diversity reports (e.g., Trainee Diversity Report). If ICs receive these reports in applications or RPPRs, the IC should not review the report. These reports provide diversity related information, but do not involve specific DEI activities. ICs must use the following term: "NIH no longer requires the [name of diversity table/plans]. Therefore, NIH did not review the [name of diversity table/plans] provided. NIH funding may not be used to support any diversity, equity or inclusion (DEI) activities". Note: this section applies to diversity related reports, only. Other areas that are no longer NIH/HHS priorities/authority must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICs do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

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Category 2B:

Prospective reviews by GM where the DEI language in certain sections of the application has to be removed even though the project itself is not focused on DEI but may have language or have been awarded from a DEI NOFO that is expired/taken down for revision to go back up once the language is appropriately excised.

Examples below, and in these cases, IC should consider using the Category 2 term of award but remove the negotiation language from the term:

- Resource Section
- Biosketch
- RPPRs

Category 2C:

Subprojects terminated by HHS.

- OPERA will restrict the funds associated with the project. No action required from the IC.

Category 3: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

Category 4/HHS Departmental Authority Terminations:

- OPERA receives a list from the Director, NIH or designee.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the IC is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the IC must:
  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.

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- OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICs.

- Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
- Include the following Termination Term in the revised NOA:

  It is the policy of NIH not to prioritize [insert termination category language from Appendix 3, verbatim]. Therefore, this project is terminated. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

  NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

  - Note: Appeals language must be included **prior to** October 1, 2025. After October 1, 2025, when HHS will fully adopt 2 CFR 200, per 2 CFR 200.340, termination actions taken based on agency priorities are not appealable. This is different from terminations based on noncompliance (administrative and programmatic).

- eRA provides OPERA with daily reports on NOAs issued, so ICs do not need to report to OPERA on each action completed.

Category 5: Awards to Entities in certain foreign countries

- Additional guidance on awards to foreign entities is forthcoming. At this time, ICs should hold all awards to entities located in South Africa or countries identified on any of the following lists.
  - State Department Countries of Particular Concern
  - State Sponsors of Terrorism
  - Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern

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- Office of Foreign Assets Control Sanctions List

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

> **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

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Appendix 2 – Guidance for staff to use on specific programs, awards, supplements.

- **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
- **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated.
- **Linked (or equivalent) Awards**: If one linked award is terminated, the IC is only required to terminate the specific award noted in the letter. The is should review and determine whether terminating that ward will have a structural impact on the scientific outcome originally intended by the IC and act as appropriate on the remaining awards.
- **Diversity Tables** – Ignore and issue the grant using the term provided above.
- **Diversity Plans** – Ignore and issue the award using the term provided above.

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Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports. Use this language for HHS terminations only.

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.
- Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.
- COVID: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

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Appendix 4 - Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

From: Memoli, Matthew (NIH/OD) [E]
To: Bundesen, Liza (NIH/OD) [E]
Cc: Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject: Re: Clean Version of DEI Restriction Term - Final
Date: Friday, February 28, 2025 2:54:19 PM

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approved

Matt

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From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs, Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
Liza

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Appendix 5 – Notice of Funding Opportunity (NOFO) Guidance

[pending]

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Appendix 6 – Frequently Asked Questions

1. **When reviewing applications for activities that are no longer an NIH/HHS priority/authority, should ICs review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICs do not need to review Other Support for alignment with NIH/HHS priorities/authority.

2. **For phased awards where the second phase (i.e., Type 4) will not be awarded due to NIH/HHS priority/authority, how should the IC notify the recipient that the Type 4 will not be issued?**

   OPERA is following up on this question, and will provide additional guidance, when available.

3. **When revising awards to terminate a project, how should the IC respond to red bars in SEAR?**

   The IC should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICs can clear the SEAR flag with a comment that the project is being terminated.

4. **If a project is terminated on an HHS list or a Type 5 is withheld because the project is no longer an NIH/HHS priority/authority, can the IC issue a subsequent Type 2 award?**

   No. If a project has been terminated due to agency priorities, it is no longer eligible for a renewal award.

5. **For recipients of K awards that are terminated due to NIH/HHS priority/authority, will eligibility requirements be modified to allow the individual to apply for another K award?**

   OER is reviewing this policy and will provide additional guidance, when available.

6. **When ICs issue revised NOAs to terminate awards, do they have to use the exact language provided by HHS in the termination term?**

   Yes, ICs must use the exact language provided in Appendix 3, with no edits.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards, when termination letter is issued.

Recipients are required to request approval from OPERA before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare. These are the only approvals that will be issued. OPERA will work with the IC to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS.

Recipients are required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

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From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: Perry Jones, Aretina (NIH/NIDDK) [E]; Rosenberg, Mary (NIH/NIDDK) [E]; Curling, Mitchell (NIH/NIDDK) [E]
Subject: Staff Guidance - Updates Made during GMAC
Date: Wednesday, May 07, 2025 4:04:00 PM
Attachments: NIH Grants Management Staff Guidance - Alignment with Priorities - Draft - 5.7.2025 Updates.pdf

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Updated staff guidance based on discussions…

- Emphasize that whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.
- Updated term language to note that requests for ICO reconsiderations should be sent to the IC Director.
- Updated Category 2 when ICOs are unable to remove activities that are not an NIH/HHS priority. ICOs do not need to work with OPERA on the bilateral termination, rather, OPERA must be notified, for tracking purposes.
- Updated Category 2B. Noted that ICOs should document any changes to the title or abstract in the grant file.
- Category 2:
  - Added term for bilateral terminations.
  - Clarified that for unilateral terminations, the ICO must issue a letter as outlined in Termination Type 3 – ICO determinations
- Category 4: Added a note referencing NOT-oD-25-104. At this time, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities that include a subaward to a foreign entity.
- Appendix 8: Updated template letter, to be used for ICO determinations, to reflect ICO reconsideration language and IC CGMO as signatory.
- Added FAQ on negotiating with conference grant recipients to remove DEI sessions or activities.

Reminder – we will finalize once we receive the memo from the Director.

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

Category 1: The sole purpose of the project is related to an area that is no longer an NIH/HHS priority/authority (e.g., diversity supplements, diversity fellowships, or conference grant where the purpose of the meeting is diversity, etc. after the priorities memo is issued), and/or the application was received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
  - Include the following term in the revised NOA:

    Term of Award:

    Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

    Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

    This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For second and third NCE's, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately end the grant project (use disapproved extension term below). If the non-NIH/HHS priority/authority research activities are ancillary to the project, approve the extension (use approved extension term below). Reminder – even if a grant project is in an NCE, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's may use the following term of award when approving/disapproving NCEs:
  - **Term of Award (approved extension):** The no-cost extension has been approved for this project to support an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, etc.] research or research training activities or programs. Any funds used to support such activities will result in a disallowance of costs, and funds will be recovered.
  - **Term of Award (disapproved extension**): The no cost extension request for this project has been denied. Please proceed with orderly phaseout of the project. NIH grant funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs.

Category 2: Project partially supports non-NIH/HHS priority/authority activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope). This means the non-NIH/HHS priority/authority activities are ancillary to the purpose of the project, in some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the Restriction Term of Award (see Action 2) in Section IV of the Notice of Award. No exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding ICO must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file. The recipient/awardee cannot rebudget these funds, they must be recovered by the IC.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - Sample language for requesting application updates from the AOR: It is the policy of NIH not to prioritize [select one of the following: diversity, equity and inclusion (DEI) research programs, or other non-HHS/NIH priorities, or countries of concern]. [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section

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[XXXX] of your application. Please work with the PD/PI to update the application sections and adjust the budget as appropriate to remove all [insert appropriate activity] activities and submit these updates to the Program Official and Grants Management Specialist for review and approval.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.

- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, issue the award and include the following Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.

Term of Award (Approved 2/28/2025 – Refer to Appendix 4 for the approval from Dr. Memoli):

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa, etc.] research or related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes [select one of the following: diversity, equity and inclusion (DEI) research programs, vaccine hesitancy, climate change, etc.] or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

  NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

  Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award.

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

  Term of Award: The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO must work with the applicant/recipient to open the conference up to all populations. If a negotiation to broaden the target audience is not feasible, or the conference is no longer viable, then the ICO must terminate the award following the process in **Category 1**.
- **Diversity Reports (e.g., Ts, R25, K12, and any others):** NIH is modifying the application instructions and RPPR instructions to remove requirements for diversity reports (e.g., Trainee Diversity Report). If ICO's receive these reports in applications or RPPRs, the IC should not review the report. These reports provide diversity related information, but do not involve specific DEI activities. ICO's must use the following term: "NIH no longer requires the [name of diversity table/plans]. Therefore, NIH did not review the [name of diversity table/plans] provided. NIH funding may not be used to support any diversity, equity or inclusion (DEI) activities". Note: this section applies to diversity related reports, only. Other areas that are no longer NIH/HHS priorities/authority must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICO's do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

Category 2B:

Prospective reviews by GM where the DEI and/or language in certain sections of the application has to be removed even though the project itself is not focused on DEI but may have language or have been awarded from a DEI NOFO that is expired/taken down for revision to go back up once the language is appropriately excised.

Examples below, and in these cases, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

> [Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": State Department Countries of Particular Concern
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: State Sponsors of Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or Office of Foreign Assets Control Sanctions List, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

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Type 1: HHS Departmental Authority Terminations.

- OPERA receives a list from the Director, NIH or designee.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the ICO is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the ICO must:

  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

NIH is taking this action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

- Note: Appeals language must be included **prior to** October 1, 2025. After October 1, 2025, when HHS will fully adopt 2 CFR 200, per 2 CFR 200.340, termination actions taken based on agency priorities are not appealable. This is different from terminations based on noncompliance (administrative and programmatic).

- eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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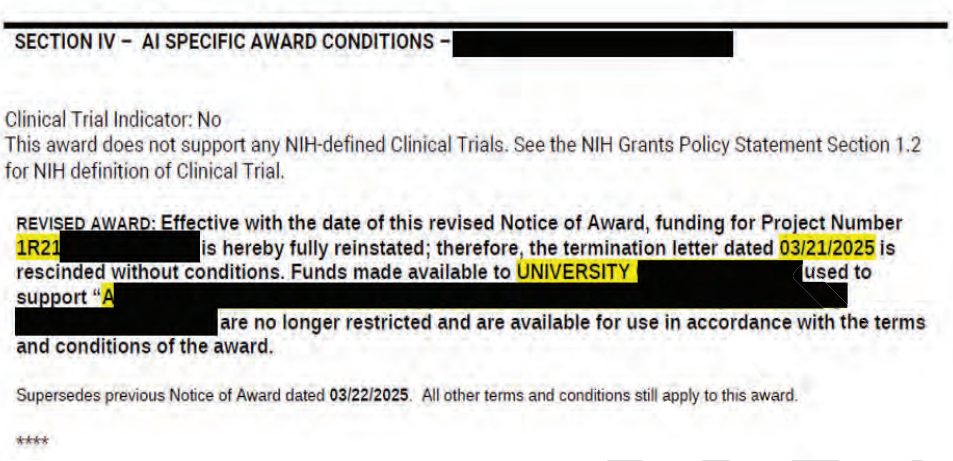
2: Type OD NIH



SECTION IV – AI SPECIFIC AWARD CONDITIONS – [redacted]

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: Effective with the date of this revised Notice of Award, funding for Project Number 1R21[redacted] is hereby fully reinstated; therefore, the termination letter dated 03/21/2025 is rescinded without conditions. Funds made available to UNIVERSITY [redacted] used to support "A[redacted] are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated 03/22/2025. All other terms and conditions still apply to this award.

****

Directed Terminations.

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the IC is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the ICO must:

- Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be

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terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.

- Include the following Termination Term in the revised NOA:

  This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

  Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

  This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

      Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

      This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
  - Include the following Termination Term in the revised NOA:

    This award is bilaterally terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

    Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

Impacts on the Biomedical Workforce:

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- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for instructions on submitting waiver requests.

- **Early-Stage Investigators (ESI):**

    - Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators – who are working under strict eligibility timelines – to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.

    - **Restoring ESI status:** Investigators lose their ESI eligibility when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.

- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.

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This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

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Appendix 2 – Guidance for staff to use on specific programs, awards, supplements.

- **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
- **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated.
- **Linked (or equivalent) Awards**: If one linked award is terminated, the ICO is only required to terminate the specific award noted in the letter. The is should review and determine whether terminating that ward will have a structural impact on the scientific outcome originally intended by the ICO and act as appropriate on the remaining awards.
- **Diversity Tables** – Ignore and issue the grant using the term provided above.
- **Diversity Plans** – Ignore and issue the award using the term provided above.

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Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

- China: "Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives."
- DEI: "Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs." **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- Vaccine Hesitancy: "It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria."
- COVID (to be used for HHS/NIH OD directed terminations only): "The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary." **Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

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Appendix 4 – Approved Term – Use for all Category 2 awards, i.e., renegotiated aims and associated budgets. Approval embedded below. ICO's should use this term in the IC specific award conditions.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

From: Memoli, Matthew (NIH/OD) [E]
To: Bundesen, Liza (NIH/OD) [E]
Cc: Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject: Re: Clean Version of DEI Restriction Term - Final
Date: Friday, February 28, 2025 2:54:19 PM

---

approved

Matt

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From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs, Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
Liza

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals

- **Prioritization of NOFOs**

Owner	Action
ICO	• Sends a priority list of upcoming NOFOs in two categories: **1)** those that already have Concept Clearance (Option A)[1]. **2)** those requiring Concept Clearance (Option B). Note: This is a temporary step while process is being refined.
Guide	• Maintains the data on ICO records, approvals needed (for example concept clearance), and priorities for publication in ICO Guide priorities spreadsheet.

- **Creation of Forecast Records**

Owner	Action
ICO	• Creates a **forecast** in FOAM for NOFOs prior to concept clearance and at least **6 months** prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained. ○ Create a **Forecast** record. ○ Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact. ○ Click "Save". ○ Click "Create NOITP" button within the NOFO record. ○ Select most recent *Forecast Template*. ○ Click "Save". ○ Go to *Content* and fill in required fields (red asterisks). ○ Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required. ○ Note: the forecast *Description* section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. ○ Save record and notify the Guide when the forecast is ready for leadership approval (see below). • Sends email to the Guide mailbox when ready for leadership approval ○ NIH Guide (NIH/OD) nihguide@OD.NIH.GOV ○ Subject: NOITP ###-##-##-###– [IC Name] – [Desired Clearance Date] ▪ Note: the number is important because of the variety of draft versions in FOAM. ▪ Plan to implement FOAM task in future to remove dependence on email.

[1] For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are **not approved.**
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of **approvals** and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to "published" in FOAM once the content has been fully approved. • Notifies **OPERA** of the status via email.
OPERA	• Sends Forecast report to HHS[2] . • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a "compare documents" of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. **Note:** FOAM has a compare documents feature.

[2] Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If **no changes** to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

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Appendix 6 – Frequently Asked Questions

1. **When reviewing applications for activities that are no longer an NIH/HHS priority/authority, should ICO's review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICO's do not need to review Other Support for alignment with NIH/HHS priorities/authority.

2. **For phased awards where the second phase (i.e., Type 4) will not be awarded due to NIH/HHS priority/authority, how should the ICO notify the recipient that the Type 4 will not be issued?**

   In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

3. **When revising awards to terminate a project, how should the ICO respond to red bars in SEAR?**

   The ICO should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICO's can clear the SEAR flag with a comment that the project is being terminated.

4. **If a project is terminated on an HHS list or a Type 5 is withheld because the project is no longer an NIH/HHS priority/authority, can the ICO issue a subsequent Type 2 award?**

   No. If a project has been terminated due to agency priorities, it is no longer eligible for a renewal award.

5. **For recipients of K awards that are terminated due to NIH/HHS priority/authority, will eligibility requirements be modified to allow the individual to apply for another K award?**

   Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. **If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

   Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

7. **When ICO's issue revised NOAs to terminate awards, do they have to use the exact language provided by HHS in the termination term?**

   Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

8. **Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

   No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. **If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?**

   Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. **If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?**

    Yes. All monetary revisions are subject to this guidance.

11. **Can ICO's approve requests from recipients to modify the project title?**

    Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. **When ICO's receive questions from recipients regarding HHS terminations, what should they do?**

    ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. **For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?**

    An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. **What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?**

    For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with 2 CFR 200.340(a)(4). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. **When will the Final RPPR become available for recipients to prepare and submit?**

    The F-RPPR link will open once the project period has ended.

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16. **Can recipients draw down funds after the stated termination date?**

    For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. **When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?**

    The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. **Will recipients have the standard 120-day period following the termination date to submit closeout reports?**

    Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. **If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?**

    Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. **For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?**

    When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. **If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?**

    Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. **Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.**

    The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. **If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?**

    No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. **For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?**

    Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. **For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?**

    Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. **If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?**

    No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. **If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?**

    Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. **For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.**

    In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement, and 2 C.F.R. § 200.340(a)(4). This letter serves as a termination notice.

The 2024 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations for federal grants are generally determined by the laws, regulations, and terms in effect at the time the grant was awarded, as outlined in the Notice of Award (NOA) or grant agreement". This "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."

According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340." At the time your grant was issued, 2 C.F.R. § 200.340(a)(4) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This project no longer effectuates agency priorities. [insert termination category language (e.g., DEI) verbatim]. Therefore, there is no modification of the project that would align with agency priorities.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision," no corrective action is possible here.

Costs resulting from financial obligations incurred after termination are not allowable. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §200.344. However, due to the immediate termination of this project, NIH may require a shortened timeframe to submit closeout reports. Details will be provided in the revised NOA issued by the Grants Management Official.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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Termination Categories

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Gender: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.
- Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

National Institutes of Health
Office of Extramural Research

[Letter Date]

[AOR Name]
[Recipient Name]
[AOR email address]

Commented [KG1]: eRA: OPERA confirmed the Business Official for the award record is fine.

Dear [AOR Name]:

Effective with the date of this letter, funding for Project Number [PROJECT NUMBER] is hereby terminated pursuant to the Fiscal Year [Award FY] National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The [Award FY] Policy Statement applies to your project because NIH approved your grant on [Budget Period Start Date], and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The [Award FY] Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. [Insert reason for termination using language provided (e.g., DEI, gender, China, Vaccine Hesitancy)]

Commented [KG2]: eRA: OPERA will provide the category information for each grant with the list of applications to drive which text should be inserted.

[If China, insert text below in-line above]

[Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

contravenes American national-security interests and hinders America's foreign-policy objectives.]

[If DEI, insert text below in-line above]

[Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.]

[If Gender, insert text below in-line above]

[Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.]

[If Vaccine Hesitancy, insert text below in-line above]

[It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.]

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal

[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).

Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Commented [KG3]: eRA: Also providing the image file. Please advise if need anything different.

Michelle G. Bulls, on behalf [IC Chief GMO Name], Chief Grants Management Officer, [IC Name]
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

Commented [KG4]: eRA: Can we remove is text if OD award?

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

From:	Bulls, Michelle (NIH/OD) [E]
To:	Chief GMOs
Cc:	EPMC Principals; Curling, Mitchell (NIH/NIDDK) [E]
Subject:	Staff Guidance - Updates Made during GMAC - 5/12
Date:	Thursday, May 15, 2025 9:57:00 AM
Attachments:	NIH Grants Management Staff Guidance - Alignment with Priorities - Draft - 5.12.2025 Updates.pdf

5/15: New Updates from those below:

- NCE section - addressed second and beyond.
- ICO reconsideration section – removed the CGMO as POC and replaced w/IC Director.

5/7: Updated staff guidance based on discussions…

- Emphasize that whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.
- Updated term language to note that requests for ICO reconsiderations should be sent to the IC Director.
- Updated Category 2 when ICOs are unable to remove activities that are not an NIH/HHS priority. ICOs do not need to work with OPERA on the bilateral termination, rather, OPERA must be notified, for tracking purposes.
- Updated Category 2B. Noted that ICOs should document any changes to the title or abstract in the grant file.
- Category 2:
  - Added term for bilateral terminations.
  - Clarified that for unilateral terminations, the ICO must issue a letter as outlined in Termination Type 3 – ICO determinations
- Category 4: Added a note referencing NOT-oD-25-104. At this time, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities that include a subaward to a foreign entity.
- Appendix 8: Updated template letter, to be used for ICO determinations, to reflect ICO reconsideration language and IC CGMO as signatory.
- Added FAQ on negotiating with conference grant recipients to remove DEI sessions or activities.

Reminder – we will finalize once we receive the memo from the Director.

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

Category 1: The sole purpose of the project is related to an area that is no longer an NIH/HHS priority/authority (e.g., diversity supplements, diversity fellowships, or conference grant where the purpose of the meeting is diversity, etc. after the priorities memo is issued), and/or the application was received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
  - Include the following term in the revised NOA:

    Term of Award:

    Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

    Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

    This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For all NCE requests, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately end the grant project (use disapproved extension term below). If the non-NIH/HHS priority/authority research activities are ancillary to the project, approve the extension (use approved extension term below). Reminder – even if a grant project is in an NCE, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's may use the following term of award when approving/disapproving NCEs:
  - **Term of Award (approved extension):** The no-cost extension has been approved for this project to support an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, etc.] research or research training activities or programs. Any funds used to support such activities will result in a disallowance of costs, and funds will be recovered.
  - **Term of Award (disapproved extension**): The no cost extension request for this project has been denied. Please proceed with orderly phaseout of the project. NIH grant funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs.

Category 2: Project partially supports non-NIH/HHS priority/authority activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope). This means the non-NIH/HHS priority/authority activities are ancillary to the purpose of the project, in some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the Restriction Term of Award (see Action 2) in Section IV of the Notice of Award. No exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding ICO must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file. The recipient/awardee cannot rebudget these funds, they must be recovered by the IC.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - Sample language for requesting application updates from the AOR: It is the policy of NIH not to prioritize [select one of the following: diversity, equity and inclusion (DEI) research programs, or other non-HHS/NIH priorities, or countries of concern]. [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section

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[XXXX] of your application. Please work with the PD/PI to update the application sections and adjust the budget as appropriate to remove all [insert appropriate activity] activities and submit these updates to the Program Official and Grants Management Specialist for review and approval.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.

- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, issue the award and include the following Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.

Term of Award (Approved 2/28/2025 – Refer to Appendix 4 for the approval from Dr. Memoli):

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa, etc.] research or related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes [select one of the following: diversity, equity and inclusion (DEI) research programs, vaccine hesitancy, climate change, etc.] or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

  NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

  Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award**.**

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

  Term of Award: The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO must work with the applicant/recipient to open the conference up to all populations. If a negotiation to broaden the target audience is not feasible, or the conference is no longer viable, then the ICO must terminate the award following the process in **Category 1**.
- **Diversity Reports (e.g., Ts, R25, K12, and any others):** NIH is modifying the application instructions and RPPR instructions to remove requirements for diversity reports (e.g., Trainee Diversity Report). If ICO's receive these reports in applications or RPPRs, the IC should not review the report. These reports provide diversity related information, but do not involve specific DEI activities. ICO's must use the following term: "NIH no longer requires the [name of diversity table/plans]. Therefore, NIH did not review the [name of diversity table/plans] provided. NIH funding may not be used to support any diversity, equity or inclusion (DEI) activities". Note: this section applies to diversity related reports, only. Other areas that are no longer NIH/HHS priorities/authority must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICO's do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

Category 2B:

Prospective reviews by GM where the DEI and/or language in certain sections of the application has to be removed even though the project itself is not focused on DEI but may have language or have been awarded from a DEI NOFO that is expired/taken down for revision to go back up once the language is appropriately excised.

Examples below, and in these cases, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

> [Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": State Department Countries of Particular Concern
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: State Sponsors of Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or Office of Foreign Assets Control Sanctions List, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

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Type 1: HHS Departmental Authority Terminations.

- OPERA receives a list from the Director, NIH or designee.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the ICO is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the ICO must:

  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.

    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

NIH is taking this action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

- Note: Appeals language must be included **prior to** October 1, 2025. After October 1, 2025, when HHS will fully adopt 2 CFR 200, per 2 CFR 200.340, termination actions taken based on agency priorities are not appealable. This is different from terminations based on noncompliance (administrative and programmatic).

- eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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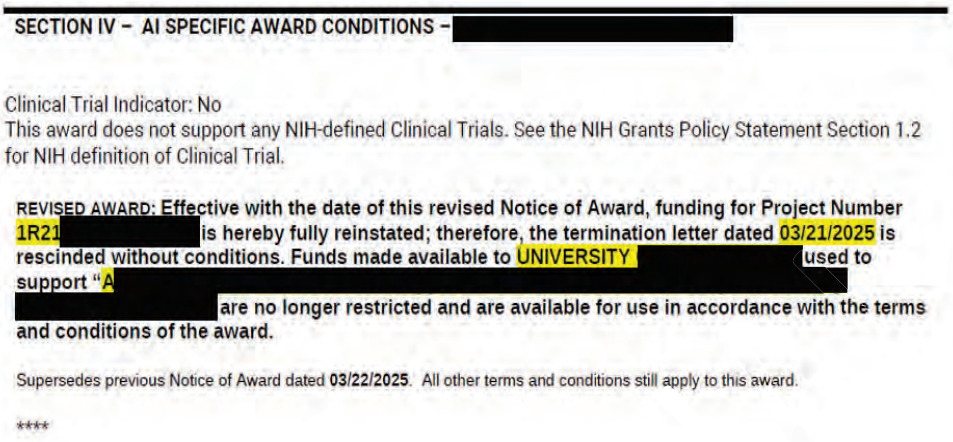
2: Type NIH OD



SECTION IV – AI SPECIFIC AWARD CONDITIONS – [redacted]

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: Effective with the date of this revised Notice of Award, funding for Project Number 1R21[redacted] is hereby fully reinstated; therefore, the termination letter dated 03/21/2025 is rescinded without conditions. Funds made available to UNIVERSITY [redacted] used to support "A[redacted] are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated 03/22/2025. All other terms and conditions still apply to this award.

****

Directed Terminations.

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the IC is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the ICO must:

- Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be

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terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.

- Include the following Termination Term in the revised NOA:

  This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

  Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

  This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

      Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

      This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
  - Include the following Termination Term in the revised NOA:

    NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

    Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

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Impacts on the Biomedical Workforce:

- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for instructions on submitting waiver requests.

- **Early-Stage Investigators (ESI):**

    - Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators – who are working under strict eligibility timelines – to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.

    - **Restoring ESI status:** Investigators lose their ESI eligibility when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.

- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.

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This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

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Appendix 2 – Guidance for staff to use on specific programs, awards, supplements.

- **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
- **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated.
- **Linked (or equivalent) Awards**: If one linked award is terminated, the ICO is only required to terminate the specific award noted in the letter. The is should review and determine whether terminating that ward will have a structural impact on the scientific outcome originally intended by the ICO and act as appropriate on the remaining awards.
- **Diversity Tables** – Ignore and issue the grant using the term provided above.
- **Diversity Plans** – Ignore and issue the award using the term provided above.

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Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

- China: "Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives."
- DEI: "Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs." **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- Vaccine Hesitancy: "It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria."
- COVID (to be used for HHS/NIH OD directed terminations only): "The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary." **Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

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Appendix 4 – Approved Term – Use for all Category 2 awards, i.e., renegotiated aims and associated budgets. Approval embedded below. ICO's should use this term in the IC specific award conditions.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

From: Memoli, Matthew (NIH/OD) [E]
To: Bundesen, Liza (NIH/OD) [E]
Cc: Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject: Re: Clean Version of DEI Restriction Term - Final
Date: Friday, February 28, 2025 2:54:19 PM

---

approved

Matt

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From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs, Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
Liza

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals

- **Prioritization of NOFOs**

Owner	Action
ICO	• Sends a priority list of upcoming NOFOs in two categories: **1)** those that already have Concept Clearance (Option A)[1]. **2)** those requiring Concept Clearance (Option B). Note: This is a temporary step while process is being refined.
Guide	• Maintains the data on ICO records, approvals needed (for example concept clearance), and priorities for publication in ICO Guide priorities spreadsheet.

- **Creation of Forecast Records**

Owner	Action
ICO	• Creates a **forecast** in FOAM for NOFOs prior to concept clearance and at least **6 months** prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained. ○ Create a **Forecast** record. ○ Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact. ○ Click "Save". ○ Click "Create NOITP" button within the NOFO record. ○ Select most recent *Forecast Template*. ○ Click "Save". ○ Go to *Content* and fill in required fields (red asterisks). ○ Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required. ○ Note: the forecast *Description* section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. ○ Save record and notify the Guide when the forecast is ready for leadership approval (see below). • Sends email to the Guide mailbox when ready for leadership approval ○ NIH Guide (NIH/OD) nihguide@OD.NIH.GOV ○ Subject: NOITP ###-##-##-###– [IC Name] – [Desired Clearance Date] ▪ Note: the number is important because of the variety of draft versions in FOAM. ▪ Plan to implement FOAM task in future to remove dependence on email.

[1] For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are **not approved.**
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of **approvals** and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to "published" in FOAM once the content has been fully approved. • Notifies **OPERA** of the status via email.
OPERA	• Sends Forecast report to HHS[2] . • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a "compare documents" of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. **Note:** FOAM has a compare documents feature.

[2] Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If **no changes** to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

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Appendix 6 – Frequently Asked Questions

1. **When reviewing applications for activities that are no longer an NIH/HHS priority/authority, should ICO's review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICO's do not need to review Other Support for alignment with NIH/HHS priorities/authority.

2. **For phased awards where the second phase (i.e., Type 4) will not be awarded due to NIH/HHS priority/authority, how should the ICO notify the recipient that the Type 4 will not be issued?**

   In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

3. **When revising awards to terminate a project, how should the ICO respond to red bars in SEAR?**

   The ICO should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICO's can clear the SEAR flag with a comment that the project is being terminated.

4. **If a project is terminated on an HHS list or a Type 5 is withheld because the project is no longer an NIH/HHS priority/authority, can the ICO issue a subsequent Type 2 award?**

   No. If a project has been terminated due to agency priorities, it is no longer eligible for a renewal award.

5. **For recipients of K awards that are terminated due to NIH/HHS priority/authority, will eligibility requirements be modified to allow the individual to apply for another K award?**

   Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. **If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

   Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

7. **When ICO's issue revised NOAs to terminate awards, do they have to use the exact language provided by HHS in the termination term?**

   Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

8. **Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

   No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. **If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?**

   Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. **If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?**

    Yes. All monetary revisions are subject to this guidance.

11. **Can ICO's approve requests from recipients to modify the project title?**

    Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. **When ICO's receive questions from recipients regarding HHS terminations, what should they do?**

    ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. **For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?**

    An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. **What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?**

    For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with 2 CFR 200.340(a)(4). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. **When will the Final RPPR become available for recipients to prepare and submit?**

    The F-RPPR link will open once the project period has ended.

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16. **Can recipients draw down funds after the stated termination date?**

    For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. **When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?**

    The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. **Will recipients have the standard 120-day period following the termination date to submit closeout reports?**

    Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. **If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?**

    Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. **For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?**

    When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. **If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?**

    Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.

The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?

No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?

Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?

Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?

No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?

Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.

In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement, and 2 C.F.R. § 200.340(a)(4). This letter serves as a termination notice.

The 2024 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations for federal grants are generally determined by the laws, regulations, and terms in effect at the time the grant was awarded, as outlined in the Notice of Award (NOA) or grant agreement". This "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."

According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340." At the time your grant was issued, 2 C.F.R. § 200.340(a)(4) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This project no longer effectuates agency priorities. [insert termination category language (e.g., DEI) verbatim]. Therefore, there is no modification of the project that would align with agency priorities.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision," no corrective action is possible here.

Costs resulting from financial obligations incurred after termination are not allowable. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §200.344. However, due to the immediate termination of this project, NIH may require a shortened timeframe to submit closeout reports. Details will be provided in the revised NOA issued by the Grants Management Official.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS (Boston)

No. 1:25-cv-10814-WGY

COMMONWEALTH OF MASSACHUSETTS, et al,
Plaintiffs

vs.

ROBERT F. KENNEDY, JR., et al,
Defendants

****

For Hearing Before:
Judge William G. Young

Preliminary Injunction

United States District Court
District of Massachusetts (Boston.)
One Courthouse Way
Boston, Massachusetts 02210
Thursday, May 8, 2025

****

REPORTER: RICHARD H. ROMANOW, RPR
Official Court Reporter
United States District Court
One Courthouse Way, Room 5510, Boston, MA 02210
rhr3tubas@aol.com

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For Defendants

P R O C E E D I N G S

(Begins, 11:30 a.m.)

THE CLERK: The Court will hear Civil Action 25-10814, the Commonwealth of Massachusetts, et al versus Robert F. Kennedy, Jr., et al.

THE COURT: Good morning. The Court has authorized internet access to these proceedings, and so I should say, if anyone has accessed the proceedings via the internet, you must keep your microphone muted, the rules of court remain in full force and effect, and that is to say there is no taping, streaming, rebroadcast, screen shots, or other transcription of these proceedings.

With that stated, would counsel introduce themselves, starting with the plaintiffs.

MR. CEDRONE: Good morning, your Honor, Gerard Cedrone from the Massachusetts Attorney General's Office representing the Commonwealth, and I'll be arguing for the plaintiffs today, and I'll let my co-counsel introduce themselves as well.

MS. DIRKS: Good morning, your Honor, Katherine Dirks from the Massachusetts Attorney General's Office.

MS. TONNU: Good morning, your Honor, Sophia TonNu for the State of California.

THE COURT: Good morning to you.

MS. ARSLANIAN: Good morning, your Honor. Vanessa Arslanian also from the Massachusetts Attorney General's Office.

MR. PAPPAVASELIO: Good morning, your Honor, Chris Pappavaselio from the Massachusetts Attorney General's Office.

MS. BROWN: Good morning, your Honor, Rachel Brown from the Massachusetts Attorney General's Office.

THE COURT: Good morning to you all.

MR. PORTS: Good morning, your Honor, Tom Ports from the U.S. Department of Justice representing all the United States defendants.

MR. KHETARPAL: Good morning, your Honor, Anuj Khetarpal for the United States.

THE COURT: And good morning to you.

Um, something off the record first. Would counsel come up to the sidebar.

(Off the record.)

THE COURT: And I thank counsel.

So at the sidebar I mentioned, and everyone recognizes, that in this case there is a significant issue of subject matter jurisdiction, and, um, every court has the inherent power to take the time to determine, in a thoughtful way, whether it has subject matter jurisdiction.

It's the plaintiffs who claim that this is the appropriate court and I think we'll start with the plaintiffs, 10 minutes a side. You'll understand I've read all of the papers that are, I think, germane to this issue. And again, as I mentioned at the sidebar, once this issue is argued, 10 minutes on this jurisdictional issue per side, I -- we will talk about whether we take another break.

Mr. Cedrone.

MR. CEDRONE: Good morning, your Honor, and thank you.

This Court clearly has jurisdiction to decide the claims in this case. The plaintiffs are bringing APA claims challenging the government policy and bringing constitutional and ultra vires claims challenging that policy. Those claims are squarely within this Court's jurisdiction under ordinary jurisdictional principles.

THE COURT: All right. Real world, what about the order of the Supreme Court to my colleague in another perhaps dissimilar case, but related to this?

Go ahead.

MR. CEDRONE: And the ***Nken*** matter, that is, um, an emergency docket order, it has limited precedential value, but we recognize it's an order of the Supreme Court that this Court has to take seriously. Our case

is different from that case.

As the Supreme Court understood the claims in that case, the claimants were seeking, among other things, a payout of the past-due amounts on contract. We're not seeking anything of the sort here.

Our argument is --

THE COURT: But you are as a practical matter. I mean this is quite a breathtaking complaint, and I say that with respect. One of the questions that I'm going to be asking, if I was to ask it, if I determine that I have jurisdiction, is whether there's an issue of impoundment here, and, um, there's a factual dispute about that. But, um -- well you go ahead. I --

Don't you agree that that's an issue here?

MR. CEDRONE: I agree that there's a question of whether the actions the defendants have taken, from the policies that we're challenging, are lawful, but we are challenging the policies themselves, and that's what sets this case apart from the Supreme Court's decision. And I would return to the --

THE COURT: When you say they're dragging their feet in doing the things they're supposed to do and going before the appropriate counsel with functionally the fact that they will get by -- I mean these are aggressive allegations, get by subterfuge the result

even if their declared purposes are held to be unlawful. I mean officers of the United States, if I declare their declared purposes to be unlawful, they drag their feet, the money isn't spent, October 1 then comes, and it lapses.

You're concerned about that, right? Money?

MR. CEDRONE: That's correct. And the Supreme Court has long made clear, going back to the decision in ***Bowen***, which is still good law, and which the Supreme Court recognized and reaffirmed in that minute order, that just because a case involves money or just because a decision will implicate the payout of money down the line does not transform it into a contract claim.

And just to -- I want to be incredibly clear, your Honor mentioned the claims about the federal government dragging its feet. Those claims are not subject to the Tucker Act argument, there is no argument that --

THE COURT: And that's a problem, I think, for the government officials here. But we'll deal with that in their argument. I'm going to say, "Well then where do those things get resolved?" If those things were true, um, what court is going to hear you?

Go ahead.

MR. CEDRONE: I think that's exactly right. And I think the fact that our undue delay claims and our

constitutional claims are "other piece" with our APA claims, and when I say "APA," I mean not the undue delay, but the more traditional arbitrary and capricious Section 706(2) claims. The fact that they're all "other piece" demonstrates that the heart of our suit is not a suit for contractual damages.

And just to give your Honor some comfort about the Supreme Court's order, we cite, at Footnote 4 of our reply brief, a number of decisions since the Supreme Court's order that have recognized the government is reading that emergency decision, it's giving that decision far more weight than it can bear. And so we acknowledge it's a Supreme Court order, it deserves due weight, but the government's placing far too much weight on it.

And I would return the Court to the test that the First Circuit recognized, that hasn't been overturned, it originates from a D.C. Circuit case called ***Megapulse***, which says the Tucker Act applies -- to determine whether the Tucker Act applies, you look to the source of the rights and you look to the relief being requested.

The source of our rights here, for the APA claims -- again I'm putting aside the constitutional claims because there's no argument the Tucker Act applies to

those. For the APA claims, the source of our rights is the APA and its demand for reasoned decision-making. The essence of our claims is not that the federal government made a promise to us in contract that it then broke. Your Honor can decide this case and our claims without reading any agreement, without construing the terms of any contract. So that's the source of our rights.

And then in terms of the relief that we're seeking, we are not seeking money damages. We're not asking the Court to say "The federal defendants had an agreement with the plaintiffs, they should have paid out $500 million, they did not, therefore I'm awarding damages, a judgment in the amount of $500." We're not seeking that. We're asking the Court to hold that the policy the agency has adopted of blacklisting certain topics and defunding programs related to those topics is arbitrary and capricious, unlawful, and contrary to statute. That may have implications for the grants that have been terminated, but we're not seeking a money judgment in damages.

THE COURT: All right, I follow. About 4 more minutes.

And again, looking ahead, were it to remain here, I have to say I -- I would be interested. I'm going to

have to know what grants, presently extant, it has implications for, if you're right.

And you agree with that at least?

MR. CEDRONE: That's correct, that's absolutely correct. But ***Bowen*** makes clear that that fact doesn't turn this into a contract claim.

So in ***Bowen*** itself, the agency action at issue was that -- and it's in this case, I noted that ***Bowen*** was in ***Massachusetts vs. HHS***. In that case itself, HHS denied payments of certain Medicaid claims, they "disallowed them" in the language of that statutory regime, Massachusetts brought an Administrative Procedure Act claim, and the Supreme Court held that was not within the scope of the Tucker Act, even though, quite straightforwardly, a decision in that case would result in the payout of money.

So the California -- the decision of the ***Department of Education vs. California*** case doesn't change any of that. As multiple courts have recognized, right up to earlier this week, in the District of Rhode Island, which is supplemental authority we submitted yesterday.

THE COURT: Those -- not all those courts go your way, though if I were counting courts, the ones who have spoken to it, most do.

What's the status of the decision of the First Circuit after the, um, order of the Supreme Court?

MR. CEDRONE: I think again because the, um -- because the Supreme Court's order is an emergency decision which the Supreme Court -- the Supreme Court justices themselves have said has limited precedential value, my argument would be the First Circuit's decision stands except insofar as it, um, directly conflicts with the limited reasoning in that 2-page Supreme Court order. And even then, I think the Court needs to recognize that that was a request for a stay from the Supreme Court. So, um, I think the area of direct conflict might be pretty limited because the standard for a stay in the Supreme Court is different from the standard that the First Circuit was applying.

THE COURT: Thank you.

All right, I'll hear the United States.

MR. PORTS: Thank you, your Honor.

THE COURT: And maybe -- I really am interested in what is the status of the First Circuit decision after the order of the Supreme Court. I mean I work for the First Circuit. I of course work for the Supreme Court. But it's a -- it's a vertical system. I try to be transparent.

I had a case where I read a Supreme Court

decision, and I thought the decision required probable cause before you could get a pole camera, and I fit it right into the -- into the Supreme Court decision. There's a First Circuit decision which had considered that matter, predating the Supreme Court decision, and expressly excluded it. I was pretty snappily reversed with language which said "It's a vertical system. Unless we tell you we changed First Circuit law, pay more attention to First Circuit law." I live and learn.

Isn't that the case here?

MR. PORTS: Um, so, your Honor, in that case was it -- I guess was it a reversal by the Supreme Court of a First Circuit ruling?

THE COURT: No, it was I -- I was weaker than that, in that sense. I'm not so sure I agree that they reversed the First Circuit, they entered an order that is supreme in the circumstances. No, I built on dicta in a Supreme Court case.

MR. PORTS: Okay, your Honor.

THE COURT: But my decision was weaker and the decision of the First Circuit was more plain. I'm just saying I learned from it.

MR. PORTS: Understood, your Honor.

Here this is a very different situation. The First Circuit looked at the District Court's ruling,

which was assessing the likelihood of success on the merits regarding the Tucker Act argument, and I will say, for starters, that the facts in California and the facts here in what we're looking at really couldn't get much more similar.

THE COURT: Really?

MR. PORTS: But so I'll talk about that a little bit more.

THE COURT: But he says it's a different case.

MR. PORTS: I would respectfully disagree, your Honor.

In that case the Department of Education undertook a review, it terminated DEI-related grants, and the plaintiffs filed -- if the Court holds the docket and looks at their brief, um, Docket Number 7 on the docket from the District Court, the Court will see that the brief looks a lot like the brief that is filed here.

Now after amending their complaint and refiling the PI, they took out some of the more explicit references to the contract. They avoid bringing it up in the first motion and they don't have to talk about the contract until it comes up in their reply. But the only time they talk about the contract in that brief -- it focuses on the APA, um, is in the same way that this brief seeks to do. The only time they talk about it is

to say that the contracts or the agreements do not allow for termination for these reasons. That same issue exists here. And we talk about it, we talk about it in the reply, we talk about it in our opposition. It doesn't get much more similar than these two claims. So I'll start there.

The First Circuit said, looking at that, "We think it is likely that the plaintiffs will succeed on the merits." Looking at the same question, the Supreme Court said "We do not think -- we think it is unlikely -- that they haven't shown that it's likely they're going to succeed on the merits in the Tucker Act claim. It is likely that the Court did not have jurisdiction and that the jurisdiction is in the Court of Federal Claims."

THE COURT: But all the Supreme Court did was stay the order. You're reading it that broadly, what the Supreme Court said?

MR. PORTS: It looked at -- yes, your Honor, it stayed the order and it said, as its reasoning, that it was unlikely, um, looking at the Tucker Act, and said that the jurisdiction is likely in the Court of Federal Claims.

THE COURT: Where then -- where then are the, um, equitable claims going to be adjudicated?

MR. PORTS: Um -- okay, your Honor. So to discuss all of the claims overarching I will say one correction for what opposing counsel has said. The Tucker Act argument applies to all of the claims for -- under the APA, the constitutional claims, and the ultravirus claims. So these are all based, um, if you look at the relief.

So first, plaintiffs want the Court to compel NIH to keep paying on now-terminated grant agreements by setting aside the termination of those agreements. So on that claim involving existing grants, the Court does not have jurisdiction to issue that because the Tucker Act is the exclusive waiver of sovereign immunity to bring claims on an express or an implied contract. So that these claims are based on a contract, that's the first part of the ***Megapulse*** decision, they don't get any money under these grant agreements but for the grant agreements.

There's, um -- this is very different from ***Bowen***, there was no grant agreements there, that was just focusing on whether a statutory payment was damages or not damages. That's a different part of the Tucker Act. It's not looking at contracts, it's just saying not all money is money damages. This part that we're talking about today is about whether this is based on a

contract.

Here the relevant case is ***Ingersoll Rand***. So there the plaintiff came into the District of D.C. and said, "You arbitrarily and capriciously terminated my contract, I want review of that under the APA." And the D.C. Circuit said, in ***Ingersoll Rand***, "We can't do that, the Tucker Act is the exclusive waiver of sovereign immunity for claims to review a contract termination and it does not allow for specific performance of the contract."

Specific performance of the contract -- there is no waiver of sovereign immunity for the specific performance of the contract. The First Circuit has acknowledged that it is aware of no decision or no waiver of sovereign immunity for the specific performance of the contract. So any relief that plaintiffs can receive to get performance, or to try and get performance, um, or to get money under their contract, must be decided in the Court of Federal Claims. So that's one group.

Plaintiffs are correct in saying that the Tucker Act is not the reason that we asserted that this Court lacks jurisdiction to consider their 7061 unreasonable delay claim. So if that's what you're referring to in asking about the equitable claims, the claims for

unreasonable delay, we do believe that there is no jurisdiction to consider those claims, but for different reasons.

THE COURT: And?

MR. PORTS: For those claims we would say this Court does not have jurisdiction because it's an improper programmatic challenge, they are not seeking to compel a discrete or mandatory action, and for jurisdictional purposes, it's moot. They didn't sue until after these meetings that they're seeking to compel and these decisions that they're seeking to have made have resumed. It was -- there was a roughly a 2-month pause in communications and --

THE COURT: No, I've read your papers, but they say the clock is ticking now and it's so slow that the money's going to lapse here?

MR. PORTS: Understood, your Honor, that they do say that, um, but if the Court looks at --

THE COURT: Suppose they prove that?

MR. PORTS: Respectfully, your Honor, these documents that they have already submitted in this case disprove that. But they do prove that a pause occurred and that there is -- they're roughly 2 months behind. But that's --

THE COURT: Are you going to make that up?

MR. PORTS: Sorry, your Honor?

THE COURT: Actually I'm not so sure I can ask the question because we're talking -- but I'll ask it anyway.

Are you going to make that up? Is it all going to be determined in this fiscal year so that if they are right, the monies can be expended in accordance with the, um, appropriations that Congress made? I mean could you tell me that?

MR. PORTS: I can make a couple of points and sort of explain broadly where things stand, your Honor, if that would be helpful.

I will say, um, as far as can I guarantee that 100 percent of the appropriated money available will be appropriated by the end of the fiscal year? I cannot make that representation. But I will also say that NIH essentially never appropriates all of the money or allocates all of the money appropriated by Congress by the end of the fiscal year. That's just not what happens in any given year and it's not an impoundment problem, it is just a practical reality of NIH managing its programs and making decisions about which grants it wants to fund and which ones it doesn't want to fund. But that is very normal, it doesn't create any kind of bigger problems to not get through -- you know, um, that

whereas here, they're moving forward, they're making stuff, they are approving grants, but the fact that they may not appropriate all of the money is not an issue.

So looking at it --

THE COURT: Well it's an issue, isn't it, if the -- if this so-called "pause" was illegal, isn't that an issue?

MR. PORTS: Is it an issue?

THE COURT: You just told me, you said there's been a pause, now it's resumed. Everything's fine. But in the ordinary course, not all of the appropriated funds are going to be "committed," if that's the right word. But you say, "Well that happens every year." I mean I see and I've looked and there's a 5-year plan that's in effect on paper. But my question to you is suppose this pause was completely unlawful -- suppose, just suppose that, you're saying to me, um, that's without remedy?

MR. PORTS: I would say it is -- it is certainly without remedy where plaintiffs waited until after that pause to even bring a lawsuit, and NIH had resumed its consideration and its holding of meetings and taking all of the actions that the plaintiffs seek to compel. It's unclear what this Court would do, as far as offering a remedy, where what they're asking for is already

happening?

THE COURT: It's on them. I understand the argument. All right, this has been very helpful.

Now, I propose to take a brief recess. Let me put to you this issue. I'm going to take a recess briefly, um, in any event.

Should I -- to encourage the parties to talk, should I just simply take this matter under advisement, stay my hand in expressing any view, um, or should I get deciding it and decide it and we'll see where it comes up?

Mr. Cedrone?

MR. CEDRONE: I think a short recess would be useful. I also know that your Honor typically does not allow reply arguments --

THE COURT: I do not.

MR. CEDRONE: Is there any way I can respond to the --

THE COURT: No.

MR. CEDRONE: Okay. Thank you, your Honor.

THE COURT: You know I've read your brief. So the answer is "No."

Counsel?

MR. PORTS: Yes, your Honor, we --

THE COURT: The same -- so here's what we're going

to do. I don't mind -- I need the recess. I appreciate the argument.

We'll stake a 10-minute recess. I'm coming back on the bench. My first question is the one I just posed.

Do you want to know -- if I were able, and I'm not saying I am, but do you want to know what I think? Or even if I don't yet know what I think, do you want me to get busy on resolving this? Or, because talking is a good thing, I urge you to talk, do you want to agree to a longer wait? And I'm not talking about a great deal of time, like over the weekend, something like that. Or tell me something else? I expect an answer as to that and then we'll see what I do.

Does that make sense?

We'll take a 10-minute recess. We'll recess.

THE CLERK: All rise.

(Recess, 12:00 p.m.)

(Resumed, 12:15 p.m.)

THE COURT: What's the answer to the question?

MR. CEDRONE: Our view is that we would like a decision and we'd like to move forward, and that that does not preclude us from talking with the government and hoping to work things out so that --

THE COURT: Of course it does not. Of course it

does not. Well it would take two. And so here's where we are.

I'm going to take the matter under advisement. I'm going to commence work on it at once. To be completely transparent, my impression is that the states have the better of it and that this Court does have subject matter jurisdiction. That's not a ruling. The matter is sufficiently complex that, as the saying goes, "I've got to see how it writes." And I will. I have the right to take the time to determine this Court's subject matter jurisdiction.

If I determine that I am without jurisdiction as to one or both aspects of the case, without further meeting, I will so declare, in a very short order. If I determine that this Court has subject matter jurisdiction, um, we will meet at 2:00 p.m. on Tuesday of next week for a case-management conference. Because I will tell you now -- and don't -- please don't think that my mind is made up and therefore that's where we're going, because my mind is not made up. I thank the, um, all the attorneys, and I thank the government attorneys, the United States government attorneys for their careful presentation. But this is a motion for a preliminary injunction and expedition, if the Court has subject matter jurisdiction, um, is required.

But I don't -- I prefer to deal with matters on the merits. And so if at that -- if I think I have subject matter jurisdiction, at 2:00, Tuesday, my present intention, if I do, is to collapse further proceedings on the preliminary injunction with trial on the merits, and to discuss at that conference the most expeditious manner of trial proceedings. My feeling is that a large portion of this can be handled by summary judgment or a case-stated, but significantly not all, and, um, a trial is definitely required.

To that end, I make three requests. The first will be helpful to whatever court hears it and I want it -- and this is a request to the states. I at least would find this very helpful, and by Tuesday at 2:00 p.m. I want it. And I have every reason to believe the Court of Federal Claims will find it helpful too.

I want a list -- and I understand there's hundreds of them, but I want a list of the grants actually affected -- really on a spreadsheet, a list of the grants actually affected, not process that may affect other grants. And then across the top I want -- and you people can encapsulate the grounds why conduct with respect to that -- those grants is wrong. It's not just arbitrary and capricious, some of them you say flat out violate the governing statutes. I want to know that.

The other two requests are previous and really are not my business unless I have subject matter jurisdiction. But only in the effort to save time, I make two additional requests, one of the states and one of the federal authorities.

The next question to the states -- and I know why you stayed away from the grants, the whole argument, this isn't about contracts, but your proposed preliminary injunction is -- and I say this respectfully, is too great -- it's too general, significantly too general. I'd like -- although I suggested that my preferred course of conduct is to collapse the hearing for a preliminary injunction with trial on the merits, maybe that trial has some injunctive relief. So I want something much more specific.

I speak with some diffidence. Look, I'm a transparent person, this subject matter jurisdiction is a big issue. I'm not past it. Don't anyone think I am. But I think beyond it. Maybe it's not for me. So I ask that. I'm not looking for that at Tuesday. But if I keep the case, um, asking for a preliminary injunction when you collapse it with trial on the merits doesn't mean it doesn't go away, it means I much prefer to proceed based on evidence.

And the same -- and I ask this with the same diffidence of the federal authorities. In your presentation -- and it has been very helpful, you mentioned DEI. I understand the Administration is against DEI. This is an area, um -- the substantive area here is health care for all Americans. And so when you use that term, counsel, respectfully I just don't know what you mean? And this isn't a -- a teasing question.

I understand the words mean "Diversity Equity Inclusion." I think I know what "diversity" means. I know it's a word with a positive connotation to me. "Equity" is fairness. There can be many disputes over fairness, cases deal with those all the time. "Inclusion," I -- well I shouldn't characterize the Administration, but I understand that the federal administration has problems with inclusion. But I just don't know what it means.

There has to be some working definition. And so I'm looking for one. If I keep the case, I need a working definition. It's not "The length of the Chancellor's foot." So what does that mean?

What does that mean -- um, you know in the Education cases, that's usually coupled now with a broad reading of ***Students for Fair Admissions***, the case about

the Harvard admissions process. I can understand that. I mean I understand what the decision of the Supreme Court means. But this is health care, this is research to advance health care for all our citizens. So I don't know what it means in this circumstance. And I say that with complete honesty. I need to know what it means. And as one who may be tasked with fair and full adjudication, it's my responsibility to know what it means.

All right, I'm taking the matter under advisement. We'll stand in recess. There may or may not be a hearing on Tuesday. And just as soon as I am confident in my reasoning, I will advise you.

MR. CEDRONE: Just to confirm on your Honor's request, the spreadsheet that you requested we will prepare by?

THE COURT: I want that by Tuesday.

MR. CEDRONE: And the further requests are --

THE COURT: Even if it's a matter of only curiosity to me, I am satisfied that the Court of Federal Claims would like to see something like that. And, um, I'm not looking for a "Thank you" from them, but I want it. And you're right, I want that 2:00 Tuesday. You're in possession of this data, it's your pleading, I'm asking you to talk about your pleading in

some more detail.

The other two, um, I do make those requests with diffidence because we may not be meeting on Tuesday. If we meet on Tuesday, I want them.

MR. CEDRONE: I understand.

THE COURT: I do express my thanks to you all. We'll stand in recess.

MR. CEDRONE: Thank you, your Honor.

MR. PORTS: Thank you, your Honor.

(Ends, 12:30 p.m.)

C E R T I F I C A T E

I, RICHARD H. ROMANOW, OFFICIAL COURT REPORTER, do hereby certify that the forgoing transcript of the record is a true and accurate transcription of my stenographic notes, before Judge William G. Young, on Thursday, May 8, 2025, to the best of my skill and ability.

/s/ Richard H. Romanow 05-12-25
_____
RICHARD H. ROMANOW Date

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS (Boston)

No. 1:25-cv-10814-WGY

COMMONWEALTH OF MASSACHUSETTS, et al,
Plaintiffs

vs.

ROBERT F. KENNEDY, JR., et al,
Defendants

****

For Hearing Before:
Judge William G. Young

Case Management Conference

United States District Court
District of Massachusetts (Boston.)
One Courthouse Way
Boston, Massachusetts 02210
Tuesday, May 13, 2025

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P R O C E E D I N G S

(Begins, 2:00 p.m.)

THE CLERK: The Court will hear Civil Action 25-10814, the Commonwealth of Massachusetts, et al versus Robert F. Kennedy, Jr., et al.

THE COURT: Good afternoon. I have permitted internet access for this hearing, though it's appropriate that I say that if you are attending this hearing via the internet, you must observe all the rules of court, that is to say you must keep your microphone muted, there is to be no taping, streaming, rebroadcast, screen shots, or other transcription of these proceedings.

Well, good afternoon, counsel. You've seen the Court's order, um, and the first order of business is to -- now that I am satisfied that this court has, um, jurisdiction, to entertain the motion for a preliminary injunction. I do, after some consideration, pursuant to Federal Rule of Civil Procedure 65(a), collapse further hearing on the motion for a preliminary injunction with trial on the merits, and I am going to use this hearing as a, um, really a case management conference.

I acknowledge the -- and I appreciate the plaintiff states' listing of the specific grants which are at issue, though this does not preclude them from

coming up with additional data. I more carefully reviewed your complaint, and in fact at Paragraph 152 you say, "perhaps more than 100" actually.

What's the count here? It's 500 and something, isn't it?

MS. DIRKS: Yes, your Honor. Katherine Dirks for Massachusetts. I don't know the final tally, it might have been 563 or so. But I don't have it in front of me.

THE COURT: Well the exact amount is not important, but our count is roughly the same.

Let me take just a moment and try to explain what I'm doing.

It has been this Court's practice, when injunctive relief is sought, um, in most cases, to make use of Rule 65(a) and, um, move promptly to the merits. It has been the Court's considered opinion that a trial, with evidence, with all the safeguards of a trial, is to be preferred to affidavits where -- which I have called in other circumstances, "The Potemkin villages of modern American litigation, all lawyer-created flash and no interior architecture." I am a person who believes in cross-examination. And, um, because federal court proceedings are unfortunately too slow and too expensive, I think it makes sense to deal with the

actual reality. So I followed my usual procedure. And now -- and I say this candidly, I don't know what to do.

I had another of these cases, spawned by the actions of the current administration -- and I don't compare them in any way, and they're completely separate, but I have a case involving alleged free speech rights, and I did the same thing. And to me the case is a knotty case, but the prima facie proof seems pretty obvious. That's not obvious here. Or rather I'm not sure how to grab hold of this case.

This case primarily is an Administrative Procedure Act case. Such cases proceed usually, though I'm authorized to make modifications, on a record, and, um, the record, um, supplemented by argument, is as close as we get.

Here the case is a rather sprawling case, um, I don't mean that critically, that's just the nature of the claims here, that it is this Court's obligation now promptly to address. So I'm groping for a way to do just that, to address the claims promptly, and I am very much open to advice from counsel. This is not the only case on the Court's docket. And I recognize that many other cases have dealt with similar situations by denying or granting preliminary injunctions. We'll see if I can't get to the merits and, um, work through some

of this very promptly.

So without committing ourselves in any way, I did want to quote you something really beautiful, that we, um, held the investiture for Magistrate Judge Jessica Hedges last week and she spoke and spoke brilliantly. But there was one phrase that she used that has stuck with me, and I'm sure I will refer to it frequently. She says, "Judges must be brave, meticulous, thoughtful. They are invited to these virtues by lawyers who are brave, meticulous, and thoughtful." And that, in all candor, is what I invite now.

So here's what I'm thinking as a way to start, and I -- this does not deal will all the issues, but it promptly, or as promptly as I can conceive, deals with some. Now -- and I'll sketch it out. But don't think I'm wedded to this. I think I'm being candid.

I'm very grateful to the, um, document provided me by the plaintiffs. Let me say -- this activity in Congress about nationwide injunctions, I'm not one who believed in nationwide injunctions. I had always thought that you dealt with the parties before you, that you could bind the parties before you, give them relief and enjoin them, if necessary, but nonparties, the government could always -- they can always appeal, the right is to appeal, but the government could, as I

learned it in law school, say they don't accede to the decision of the District Court and therefore the decision of the District Court would have effect only to the parties who came before the Court and have their matters adjudicated. So I approach this case believing that that is the appropriate approach.

So this spreadsheet and these 500-and-however-many grants there are pretty much defines -- well, no, it doesn't, because you were asking for relief more prospectively as to what you're thinking comes down the Pike, and I'm not dismissing things. I guess I do want to say I was told, in one of these hearings, that there were like 800 grants. Well grants to institutions in states other than the plaintiffs' states, this Court doesn't speak to, doesn't purport to adjudicate, and I -- and any injunction, if ever an injunction were to issue, wouldn't apply, um, save as to specific grants or specific institutions, specific states that are called out. So here's what I'm thinking, but it's only a first shot.

I'm struck by the fact that the letters of termination here are -- they're not all identical, but they're virtually identical, and they were issued in March on or about just a few days. I mean they all came out in a great blast. And they set forth, as much as I

can understand, the government's position here. So let me just quote from an exemplar letter and tell you both my concerns and where I think we might fill it.

So I'm picking out one issued on March 21st to Ayain Denson, the University of Massachusetts at Amherst, and I'm just picking it out. After some citations, it, um -- and there's this paragraph, and I'll just go sentence by sentence.

"This award no longer affects agency priorities." Well one imagines that that's so, um, and I have some concern for statutory mandates. But I understand it does not. I'll accept that it does not. And then there comes this sentence.

"Research programs based on gender identity are often unscientific." I don't know that. And there's a comma. And then it says, "have little identifiable return on investment." I don't know that. Maybe that's so. And then another comma. "And do nothing to enhance the health of many Americans." I don't know that.

Then the next sentence says, "Many such studies" -- no reference to the particular study at hand here. "Many such standards ignore rather than seriously examine biological realities." I don't know that. "It is the policy of NIH not to prioritize these research programs." Again that's a policy statement. I don't

take issue with it for the moment.

The next paragraph. "Although," and then they're quoting, "NIH generally will suspend rather than immediately terminate a grant and allow a recipient an opportunity to take appropriate correction action before NIH makes a termination decision," closed quote. "No correction" -- "No corrective action is possible here." I don't see why that's so? But we could examine that.

And then on the next page, and I'm not going to quote this, but there is a reference to an "administrative appeal." That's one exemplar.

Another exemplar, um, has an added sentence, um, to what I've read -- and this one comes from a letter of the same date to a Chake Camara, the University of Massachusetts Medical School in Worcester, and after a couple of the sentences I've read, comes this sentence. "Worse, so-called Diversity, Equity, and Inclusion, DEI studies, are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans." I didn't know that. And I don't know it.

Now because these letters are common -- and you see where I'm going here, I'm, um, channeling, if you will, Justice Kagan's dissent. If there's basis for this, maybe so, but if there's no basis for these

factual statements -- put aside the ones I term "policy statements," if there's no factual basis for these statements, grant by grant, then it's arguable that they are -- the terminations are arbitrary and capricious, and the Court, on the statements alone, could, um, order an injunction that reinstates the grant, with all its terms and conditions, as though the letter never was issued.

Now that doesn't get the plaintiffs entirely where they want to go, but it gets them a significant way there, it seems to me, if that were true. Congress of course can change the laws, Congress can do that, and maybe they will. And we're talking only now about a way to start in as to these specific regs.

If in fact there are studies that support any of these factual statements, or any internal analysis that support those statements, certainly the NIH, the defendants here, they have to have the full and fair opportunity to lay that analysis out before this Court. The fact they didn't state it doesn't mean that it doesn't exist.

Likewise, perhaps it doesn't exist in writing. Perhaps some official looked -- actually looked at a grant or looked at a group of grants and came to this conclusion with some sort of analysis, and, um, the

record on which this Court could act should include affidavits from those individuals. I have to say, given the framework here, that while I would accept such affidavits, I would expect that they be produced to testify and be cross-examined.

Now that's a -- another part of the record here. If an appeal has been taken by any of these grant recipients, the appeal, the results of the appeal, and any documents that reflect the discussion, um, in the appeal, should be before the Court, and I'm entitled to look at them and see whether any of these grants -- and the grant has to be evaluated on the specifics of the grant.

At least my understanding of medical research, but I stand to be corrected, is that it -- it should take account of race and gender. Sickle-cell anemia is more prevalent in a particular race. A certain type of cancer is, um, affects Ashkenazi Jews more than other people. I believe that it is the received medical wisdom that, um, gender differences are significant in providing the best possible medical care. So it can't be that we're just going to ignore those.

And, um, when I look at -- and I've -- you filed it timely, but I've spent the time since it was filed looking at this, it really does seem that, um, many of

these grants go to study, anyway, vulnerable populations. That's how I understand the medicine to work. That doesn't seem illogical to this Court, to, um -- well these are my concerns.

So if we started there -- and in terms of procedure, if we started there, we created a record for these, the Court ruled on that record that the actions were or were not arbitrary and capricious, and then under Rule 54(d), (1) I'm required to write an opinion, and I expect to, as to each variation that, um, I may have to deal with, but I can immediately -- once I'm satisfied that I've thoroughly reviewed the record, I can immediately enter a partial judgment under Rule 54(d) because the interests of justice require it. If the states lose or a state loses or some states lose as to some grant, I'd enter judgment. An appeal from an actual record with a decision can take place.

And contrary-wise, if I entered any such injunction that a grant, the termination of the grant was arbitrary and capricious, again I'm not going to sit on it, I'm going to enter in a -- in an area where one expects that Congress -- and indeed will expect that the agency may alter its or put out different guidance, this may, um -- it would be permanent only until the legal framework changes.

And I recognize that I'm groping, but let me start with the plaintiffs.

Can you think of any way to get at this better?

MS. DIRKS: Um, your Honor, again Katherine Dirks from Massachusetts, I'll just preface by saying your comment about Judge Hedge's statement about lawyers inviting the bench, the Court to think of things a different way, that really spoke to me. I really see that as my role, and I want to thank you for that, and I think maybe I can apply some of that principle here today.

THE COURT: Thank her.

MS. DIRKS: I will.

THE COURT: There's much other wisdom in what she had to say, but that was the part I was able to quote. And you're right to pick up on it, because it inspired me.

Please.

MS. DIRKS: My invitation is as follows, and it calls for hearkening back to how we frame these allegations in our amended complaint. Which is that we are not alleging that the terminations themselves are the final agency action and we are not asking the Court to conduct an individualized review of termination decisions, or other grant-based decisions, the final

agency actions that we are challenging are the directives, the challenged directives. And we're seeking ultimately, at the end of the day, for those directives to be vacated, and for the implementation of those directives to be enjoined.

Now we realize that the implementation comes in the form of the grants we've listed here and we believe that list will grow as we confirm further details with our clients, and crafting the relief might require some individualized identification of grants, but as to liability and as to the vacatur of the agency action, it is the challenged directives and the decision-making as to those directives that we're seeking to present to the Court.

THE COURT: How do we put together the record on which the Court is going to make its decision?

MS. DIRKS: So we have initiated a conference with the Department of Justice and federal defendants on that question. As to the administrative record for the challenged directives, that will be a more finite universe because it's a discrete list of directives, and that could be somewhat contained.

Now should there -- might there be some need for discovery? Potentially, yes, your Honor, because of the fact that some of these directives have not been made

publicly available, um, and we already have seen some deposition testimony in other cases regarding some of the murkiness behind the development of those directives that might require putting someone in a chair for a 30(b)(6) deposition, for instance, and there might be some redesignation of 30(b)(6) witnesses. But we still think that the universe of discovery there is quite contained, and we could move on a very expedited schedule or a resolution of the challenged directives, both the administrative record and a very very narrowly-tailored set of discovery for those issues that might be encompassed in the administrative record.

THE COURT: How long?

MS. DIRKS: We think that 14 days for the administrative record would be sufficient. Now we have had conversations with federal defendants there, we think that is not quite what they could live with, and we understand that and will obviously let them have their turn.

THE COURT: Well let me hear from --

MS. DIRKS: But we think 14 days for that, and an additional 14 days for resolving any other fact issues that might not be encompassed in the administrative record. But that does leave the question of the implementation question, and we can visit that, your

Honor. Um -- and if I could just tag on one piece of it that might not be in the administrative record.

Our understanding -- and this is to some extent in the PI papers, is that the ultimate decision as to what grants would be terminated was not granular, it was not on a program-officer basis, rather a blast e-mail went out saying, "Here are the hundreds of grants being terminated today, program officers get your notices out." And so it really should be a finite list of e-mails.

It might not be what, um, will be defined as the "administrative record," because that might post-date the directive itself, but there is a discrete period of time in which the directives were implemented. And it does not require individual deposition testimony from every program officer, it really is, um, a request for a production of documents that would be very specifically defined and could be produced with a few e-mails, is our understanding.

So we would look to a bench trial. You know we've often discussed summary judgment versus trial and the Court has, um, indicated, at the last hearing, that there might be disputes of fact, and that we're hearing today from the Court that the Court is anticipating some sort of dispute -- some disputes of fact that would

require in-court resolution and testimony. And so our inclination would be to not do summary judgment and instead put this on for trial, trial to resolve as much as we can through proposed findings of fact, so that we identify the short list, hopefully a short list of disputed facts, we can have a condensed bench trial, um, and can move this to a final resolution as quickly as possible.

THE COURT: Thank you. And that is very helpful.

Mr. Ports, what do you think of all this? You can go back to my meandering as well and, um, give me your thoughts. I much appreciate it.

MR. PORTS: Yes, your Honor.

I'll say the United States' thinking about the case is more aligned with what your Honor seems was describing than what Mr. Dirks described with her -- involving discovery and trial and things along those lines.

As your Honor stated at the beginning, this is an APA case at core, that the Court has ruled it would be decided as an APA case. Such cases need to be decided based on the agency's stated reason at the time it took an action and the documents that it considered in taking that action.

So there is -- there's a final agency action that

plaintiffs fall back in their brief was -- it's the grant terminations, that's what we end up with as the final agency action. Which although we said can't be challenged, I'll put that aside and not revisit our argument previously on this point. But, you know, we would agree that that's final, it has a legal consequence.

Your Honor mentioned appeals. Where an appeal is ongoing, there it is not final any longer, although there was a legal consequence with the termination that has reopened the agency's decision-making and the agency has not stated its final position on the matter, it is currently considering it.

But so putting aside the appeals that are ongoing, because they've been reopened, whether terminated and have been appealed, looking just at the terminated grants where there is no appeal, as your Honor described, there are a variety of reasons that grants would no longer effectuate agency priorities.

It -- we believe that the agency could compile an administrative record for those grant terminations. As long as the record from each individual grant file could, um, with agreement, include the termination letter itself and the notice of award and the agency could avoid going through the hundreds of additional

pages that are in individualized grant files that may contain sensitive information that can't be disclosed, if we included the grant termination and the notice of award to provide those stated reasons of the agency in terminating a grant, and the background on the grant, what is the award that was terminated, then we believe we could compile an administrative record of what the agency -- the decision-maker considered in terminating those grants, in 30 days.

I will say, your Honor, that's a good deal longer than what plaintiffs had asked for here, but it is after substantial back and forth and consideration within the agency about how fast it could proceed, and it is shorter than the agency would prefer. And in asking for 30 days we are seeking to move quickly and offer the fastest possible time that we could.

After, um, you know plaintiffs identify 7 challenged directives that they say are the things that they are challenging, um, that the agency would presumably be looking at to compile administrative records for each of those purportedly-filed agency actions -- and that will require looking at what a decision-maker considered, and some of the decision-makers are no longer with the agency, and this will take time and review, and we believe that 30 days

is reasonable for that.

After that, we believe that the Court is correct, this case could be decided based on cross-motions -- well I won't say "correct." What I understood the Court was insinuating was that the case could likely be decided on cross-motions for summary judgment after that unless -- unless we were to provide a declaration or some additional justification that is not apparent in a document or on the face of the termination, in which case we understand the Court would want to allow for cross-examination. But if we did not do that, the Court would be able to review based on the record, and the termination and their justifications would rise and fall based on what is in the administrative record. And if the Court finds that it is insufficient, then, yes, we believe the Court could make its ruling based on that record.

But there is no need or justification for discovery, certainly not before an administrative record has been filed, certainly not before plaintiffs have demonstrated that the administrative record is incomplete, which we would say is a requirement.

In order to order discovery, there must first be a finding that the administrative record isn't complete and that one of the very limited circumstances that

allows for extra-record discovery exists, um, and that mostly -- that typically happens in the case of pretext. And I don't think there's any allegation that there's pretext for why these grants were terminated, it is clear on the face of the grants why the agency has said to terminate the grants.

And so we would propose that we could file the administrative record in 30 days and then the parties could file cross-motions for summary judgment thereafter, and then proceed to a prompt end and proper resolution of this matter in that way.

THE COURT: Well both of you are talking sensibly and I -- we're not going to, um -- neither one of you is going to prevail in their entirety, but that's not surprising.

This Court operates on an intentionally-practical and programmatic basis. I'm starting a significant MS-13 trial on the 2nd of June. I really think that case is going to go. I expect that it will go a couple weeks. That takes us up to the 14th of June, "Flag Day."

Whenever that case finishes, um, I'm prepared to address this case, or at least part of this case. I know the plaintiffs' allegations go further than what either one of us -- what anyone who has spoken is

talking about, and I'm not dismissing anything, though change could settle or throw it by the boards.

So if I'm going to look for you around the 16th of June, that's not for filing papers, that's for being ready to go. Clearly the NIH was prepared by March to send out these notices following these directives. So it does seem to me that I ought to have a -- now this is the 13th. I ought to have -- if we're going to have the appropriate administrative record, by Monday the 2nd of June, and briefs may be filed simultaneously with reply briefs thereafter.

And I'm getting ahead of myself, actually I work for Ms. Belmont. Let me ask her.

Assuming that the case on the 2nd of June runs two weeks, what do we have on the 16th?

THE CLERK: We're free.

THE COURT: Well we're not free now, we're --

I propose a hearing on the 16th. And I'm not one to micromanage. What the government says, um, makes sense to the Court. I want to encourage you to work out disputes, and all I can say is I'm not going anywhere. If I set this down for a hearing on the 16th of June, if that hearing is just on the record, because you've worked things out, so be it. If there's a dispute as to whether I should take evidence starting on the 16th of

June, you'll let me know. And, um, my effort will be -- though whatever order happens will happen, and then to follow it up with a written opinion just as rapidly as I can.

Now, um, if I left things like that, recognizing that there may be more to this case than we have discussed today, do the plaintiffs have any questions?

MS. DIRKS: Um, yes, your Honor. Um, not a long list. I promise.

One thing we haven't mentioned or focused on today is our unreasonable delay claim, and that does seem to be the one area that, um, would benefit most from, um, live testimony or where there was the most room for --

THE COURT: I couldn't agree more.

MS. DIRKS: -- and the most room for factual disputes.

THE COURT: But that's going to take some time. So I was positing, um -- you know this idea of cross -- I know what the -- how these cases are handled. If we get an agreed-upon record, I don't know that we -- it's not strictly cross-motions for summary judgment where as to each side I have to lean against their position, if we had an agreed-upon record, then I draw the natural and probable inferences from that record. I give both sides an equal chance to argue the disputed -- it's a

mixed question of law and fact, the arbitrary and capricious issue. I'm not answering your question, I'm going back.

So the reason -- while I agree with you, that's going to take evidence, um, and we've got to start somewhere.

Do you want to start that this week or this month?

MS. DIRKS: I guess, your Honor, I -- I stand corrected, with gratitude, that maybe I should ask the more basic question.

When you say "briefs," your Honor, are you referring to specifically Rule 56 motions for summary judgment or a legal brief in support of --

THE COURT: A legal -- in support of a final decision on the issue, as you frame it, of whether these directives are unsupportable under the Administrative Procedure Act. And they will say, "Here is the record. Here are our reasons. They're all satisfactory reasons, under the Constitution, as the legal framework." And it's not for me, the Court, to make policy determinations, if policy determinations are permissible.

There are some statutory -- at least prior Congresses have instructed the NIH, for example, to be sure that they include women in their research studies,

to be sure that they include children in their research studies, and I take it to encompass the science that, um, you want to capture the data on which proper health decisions can be made. But I don't mean to talk over you.

When do you want to go on the unreasonable delay?

MS. DIRKS: Um, so if I -- I just want to make sure I understand the proposal that I'm reacting to, your Honor.

So with June 16th, it would be, um, briefing on the, um, the grant terminations piece of the case as to the challenged directives, and without the need to get into individualized, um, grants. Right?

THE COURT: Don't you characterize what I said. We'll see.

MS. DIRKS: All right, that's why I wanted to make sure I'm clarifying it, so I can understand what we're briefing.

THE COURT: I'm -- really, I'm trying to force you into -- both of you, into an agreed-upon record. There's advantages to having an agreed-upon record. If you can't, I'll settle it. I'm not hesitant to settle it. But I'm always transparent about what I'm thinking.

So you've corrected me on my idea, my approach, and focused me more on the directives quite right. NIH

counsel properly says, "But really let's look at these directives." Work that out and, I expect on the 16th, if things work -- if things work on the 16th, I will have an agreed-upon record, I will have, um, briefs, I will hear argument, um, and if I can see my way clear to action -- but I don't promise anything on that day, but then I will take it under advisement. If I can't get my arms around it, I'll be saying, "But I want this witness" or "You can't really get there from here without something." I can't see now. But I respect you both -- I respect you all, and that's what I'm thinking.

You then say -- well let's focus on that piece. Without you characterizing it, the -- the terminations and the grant terminations piece, I hope to deal with on the 16th, to be followed by a decision, which is immediately appealable once I get the decision out, and it's based upon an agreed-upon record. That's where I'm hoping to go.

So still sticking with the plaintiffs. We haven't dealt with unreasonable delay, but are you -- do you understand that and can you work with that at least for today?

MS. DIRKS: Yes, your Honor, with one additional question. And we welcome this, your Honor, and I want to thank you for the June 16th date, because that

reflects our need for urgency.

One question. When the Court said that, um, briefs would be filed simultaneously, was that simultaneously with the administrative record, which would be due June 2nd, or simultaneous with each other?

THE COURT: No, no, no, not simultaneous with the administrative record. But it's not like you people don't know the other side. The lawyering has been, and I'm grateful, exemplary.

MS. DIRKS: Thank you, your Honor.

THE COURT: One thing that can be said about the NIH, whether it's the way they express it, I don't know the basis for that, but it's not like they're secretive about what they're doing. Okay?

MS. DIRKS: Um, that works very well, your Honor. But there's still the question pending about unreasonable delay? I'm happy to take that up now or later.

THE COURT: No, let's go now to the NIH.

My discussion with her is, um, can you work with her in that schedule?

MR. PORTS: Um, yes, your Honor, we will do our absolute best to have a record prepared by the 2nd.

THE COURT: All right. If you don't, I'm likely to, um, conclude that nothing exists. But that's

neither here nor there. But that's what I expect, on the 2nd.

Now unreasonable delay. How do you want to handle that?

MS. DIRKS: Um, your Honor, we think it makes sense to -- we could schedule it now or schedule it at another time, a second hearing on that case, your Honor. The reason why I hesitate from committing to doing -- to tackling that on the June 16th date is because there might be more need for fact-gathering there and more disputed facts that would not be contained within an administrative record because --

THE COURT: I have another hearing at 3:00.

MS. DIRKS: I'm sorry, your Honor.

THE COURT: Again, it's always the practicalities of each day. Are you suggesting I hold another status conference or are you suggesting that we go forward on the order I've entered now, and as you -- and you are working together, zealous advocates for their own position can work together, and I urge you -- I'm going to depend on it.

So what are you suggesting?

MS. DIRKS: Um, either we schedule a hearing now, your Honor, on unreasonable delay and the parties work backwards from there, the alternative would be for the

parties to propose a schedule, um, and an earliest date.

THE COURT: Why don't you -- why don't you do that and you don't have to agree on it. Your schedule may not be their schedule.

All I can say is I'm not insensitive to what I've done when I've collapsed further hearing on a preliminary injunction with trial on the merits. It's imperative that we all step up and give a reasoned, I hope to say, "brave, meticulous, and thoughtful opinion," that resolves what I am responsible for resolving at the earliest possible date. This wasn't "Okay, I collapse it with trial on the merits, when in the next year are we going to have the trial?"

So I'm going to leave you. I'm not going anywhere. Get Ms. Belmont, she's wonderful, and, um -- and it will be a status conference. It's not suddenly you come in here and I'm going to say "Well where are the witnesses?" We'll have a status conference when you know the issues that you think I need to address. But that can be as early as next week or at such other reasonable time.

MS. DIRKS: That works well, your Honor. Thank you.

THE COURT: The government?

MR. PORTS: Thank you, your Honor.

THE COURT: Good. It's good to see you. I look forward to working with you.

And again, any case can be settled. If this case is settled, a simple phone call to Ms. Belmont is all that's required. We'll stand in recess. Thank you very much.

(Ends, 2:50 p.m.)

C E R T I F I C A T E

I, RICHARD H. ROMANOW, OFFICIAL COURT REPORTER, do hereby certify that the forgoing transcript of the record is a true and accurate transcription of my stenographic notes, before Judge William G. Young, on Tuesday, May 13, 2025, to the best of my skill and ability.

/s/ Richard H. Romanow 05-16-25
_____
RICHARD H. ROMANOW Date

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS (Boston)

No. 1:25-cv-10814-WGY

COMMONWEALTH OF MASSACHUSETTS, et al,
Plaintiffs
vs.

ROBERT F. KENNEDY, JR., et al,
Defendants

No. 1:25-cv-10787-WGY

AMERICAN PUBLIC HEALTH ASSOCIATION, et al,
Plaintiffs
vs.

NATIONAL INSTITUTES OF HEALTH, et al,
Defendants

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For Hearing Before:
Judge William G. Young

Status Conference

United States District Court
District of Massachusetts (Boston.)
One Courthouse Way
Boston, Massachusetts 02210
Tuesday, June 3, 2025

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REPORTER: RICHARD H. ROMANOW, RPR
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P R O C E E D I N G S

(Begins, 11:00 a.m.)

THE CLERK: Civil Matter 25-10787, the American Public Health Association, et al vs. the National Institute of Health, et al, and 25-10814, the Commonwealth of Massachusetts et al, vs. Kennedy, et al.

THE COURT: Well good morning counsel. We won't go through having everyone introduce themselves, but when you speak, if you could remember to introduce yourself, simply so that the Court Reporter's record is accurate. Let me tee up what I think I want to do here and, um, where we're going to go.

I wanted to have this status conference because there is the second of these two related cases, and I wanted to, um, have a conference where all parties could be present and, um, see the extent and the order in which they could be consolidated. So that was my purpose in calling this conference.

Or I should say, as I have in other such hearings, I have authorized internet access to this conference. Having done so, let me say, if you are attending this conference via the internet, have in mind the rules of court remain in full force and effect, which means there's no taping, streaming, rebroadcast, screen shots, or other transcription of these proceedings.

So, um, coincident with my scheduling the conference, um, various things have been done in the, um -- I've been given a proposed schedule for further proceedings in the first of the two cases and, um, in very large measure it makes perfect sense, though I want to make some comments about it, and emendations. But I am very grateful to the parties for the manner in which you're working together.

Second, consistent with the Court's order in the first of the two cases -- or at least in the first of the two cases, the government has, consistent with the Court's order, um, filed the administrative record. Here it is. You will understand I haven't looked at it since the 2nd of June. But a question to government counsel.

Is this the record as you see it in both cases or just the first?

MR. PORTS: Thank you, your Honor. Tom Ports for the government.

This record is the -- it is the government's position that this is and will be the record for both cases. I will say that -- and we had some discussion about this earlier, um, all parties met at 9:30 today in the U.S. Attorney's Office. The United States believed, as the Court previewed the last time, that there are a

handful of discrete reasons why grants were terminated. If you look at the different paragraphs, they tend to line up across the various terminations.

We have compiled all -- everything considered directly and indirectly for those reasons. It does not include the actual termination documents for all of the PDFs in the, um, the related case. So the second-filed case, we don't have all of the actual termination documents. However we believe it is very unlikely that there will be any other reasons or justifications, and therefore this record is sufficient and contains everything directly or indirectly for that case as well.

I can represent that what I told the plaintiffs that I would suggest, in the second-filed case, is if plaintiffs would let us know or let the Court know, by the 5th, if there is any other justification that is not included in a termination record in that record, then we can promptly complete the record for the second case with anything in addition, and, um, then everything will be thoroughly complete and we'd be able to proceed with everything by the 16th. We think that's very unlikely that there are any different reasons. But, um, it is of course possible. And we think that is a way to proceed and resolve everything in Phase 1 together.

THE COURT: Thank you, that's a direct answer to

my question and I appreciate it.

Now, um --

MS. AKSELROD: Your Honor, um --

THE COURT: Yes?

MS. AKSELROD: May I respond on behalf of the APHA plaintiffs with regard to the completeness of the record or would you like me to wait on that?

THE COURT: I'd like you to wait.

MS. AKSELROD: Thank you, your Honor.

THE COURT: Saying I thank you, doesn't mean that's it. And let's jump right there.

In point of fact, um, I've been reflecting on what has been filed thus far and in two respects, um, if -- if I don't have this in the record, I expect it by the 16th. So let me start with that. If it's there, fine.

But I read Footnote 1 on this schedule for further proceedings and respectfully, um, the defense either misunderstood or mischaracterizes the Court's view. I do think the very first issue to be considered is, um, the challenged directives, and so I need a record with respect to the challenged directives.

Specifically I expect -- I've come to understand that in this iterative process, the various universities were putting out algorithms about how to write grants and, um, "Stay away from this word," and "Don't say

that," and the like, "if you're seeking a grant." So one imagines, given the speed with which the defendants acted here, that there was guidance to the people who made the determinations, or the person who made the determination, and I expect it. I expect to see it. If there's an algorithm, if there's guidance, wherever it came from, I want to see what it is. The record to be supplemented in that respect.

Second, I've also come across this database called "Grant Watch," which is really rather intriguing, um, and since everybody seems to look at Grant Watch for, um, the data concerning grants from the NIH, recognizing that this case, um, certainly in its Phase 1 is limited -- let me be very clear, is limited to grants terminated, not restored, not expired, that, um, in the first case, and the second case, the list with which we're working -- and to the extent we can pare that list down by settlement or otherwise, that's a good thing. But, um, I think Grant Watch may best qualify, um -- save the government's rights, they may want to brief this, but I think it qualifies under Federal Rule of Evidence 80317. This is like a, um -- like a "Physician's Desk Reference" or something.

So the parties are free, because the universe of grants of course goes well beyond the grant that, um,

whatever I have to say about the challenged directives, any relief, if any there is, has to do only with the, um, grants that are, at least the first phase, that are listed in the materials already filed.

So let me turn to this document now, which I do think is very helpful.

So the government, um, has filed its position on the, um, administrative record, um, and whether or not the defense agrees with it -- and that's the reason I cut counsel off, the proposal here sets forth very prompt time limits for challenging the completeness of the administrative record. I'm not going anywhere. It makes perfect sense. I seek to hold myself to the -- and hold you to the, um, what's set forth on Page 2 in Paragraph, um, 2 and 3 of the proposed schedule.

And again, the government has every right to contend that the record is complete and that the supplementation is either irrelevant or, um, it ought not be supplemented. But I've said what I'm looking for here.

Now we're on for the 16th. I propose to give you -- it's on at 10:00 on the 16th. I think we can thrash our way through the argument here in the morning, and the morning to me lasts till 1:00 -- um, from 10:00 till 1:00, I may need a brief recess, but I think we can

thrash our way through.

Now then we get to this proposed second phase. And I agree that that will be heard thereafter, um, and here I see the parties differ markedly. Let me be as helpful as I can as to what I expect will follow.

You people have shown some amenability to resolving this partially or, one can always hope, wholly, um, with respect to certain or more of the challenged grants, so I want to know, at least in general -- and I recognize this is jury-waived, but I will start off the proceedings at 10:00 on the 16th. And again, I'll do this at the sidebar. The parties can agree to private resolution, and I will say, "Well have you settled any of this, and if so, what?" And you'll tell me. And those conferences will be sealed. We won't get into substance at all. And then we'll spend the rest of the morning talking about, um, really the first phase of the case, the applicable law and what can be discerned from the administrative record.

Then close on to 1:00, I will say -- and maybe it will go faster than that, but maybe not, I will say, "Well, um, now that you've heard me" -- and I've done -- I've followed this technique in other cases, so I want you to know it now. "Now that you've heard my questions and my concerns and how I dealt with the answers and the

like, um, you tell me, do you want me to stay my hand for any particular period of time, because you could work out this part of it, or you could work out all of it, or" -- and you'd both have to agree, or you'd say, "No, we want the decision."

And then I will say, um -- but I'm giving a range here because I have no idea where we'll be at 1:00 on the 16th, I will say, um -- it goes from nothing, in which I will say, "I'll take the matter under advisement, thank you very much," and that's what you'll hear from me until, at minimum, some order comes out, and at maximum, the full opinion comes out. That's one end of the spectrum.

The other end of the -- well I'm not going to be able to -- I really am looking forward to the 16th. I have no preconceived notions about this case. I'm going to tell you the concern I have, but that's downstream.

So, um, all I'll say -- a combination like this, it won't be any opinion, but I'll say, "Well, you know I think" -- because I'm very sensitive that this started out with a preliminary injunction collapsed into trial on the merits, I'll say, "I think it's coming out, at least in this area, this way or that way or whatever." And, um, maybe I will be sufficiently confident to enter an order. Most likely I will not. But, um, the

likelihood probably will be that an order will precede the full opinion, because I will have the full record, I'll have the advantage of your briefs and your arguments, and, um, cases don't -- unlike fine wine, don't get any better with delay. So they'll be at least a partial order, probably pretty fast, on the first phase of the case. Unless you tell me the other, you say, "No, stay your hand for a week, two weeks, whatever, maybe we'll work it out."

Then, when you see the way I see this case, once that's out there, the rest of it is writing, and it implicates of course the second phase, because if it goes all the government's way, I don't see much to the second phase. And he tells me there isn't much to the second phase anyway. Maybe that's right, maybe that's not right.

If it goes significantly the plaintiff's way, the second phase is, in my mind, a different consideration. But the schedule that is posited here -- and I have full respect for the government saying that the administrative record is the, um, is appropriate, and only appropriate, um, actually the way you've written it is fully satisfactory to me, because it says -- and I'm now on Page 4 of the government's, I guess -- I take it it's the government's proposal? Yes, the defendants'

position. I think their schedule makes good sense. And, um, at least -- and I propose then to adhere to it. You said "the conclusion of the Phase 1," I propose to adopt it, and within 7 days, the motion to dismiss, within 10 days, etc., as it appears on Page 4.

Now let me stop there and ask for questions and I'll resolve whatever needs to be resolved, I hope, and then we'll move to the second of the two cases, which I hope you will tell me can be resolved on the same schedule, and the first case, we'll agree. But we haven't had everyone in court until today.

So here's my concern. And my concern is an unformulated concern, because it comes only -- I don't have the advantage of the administrative record, so candidly it comes from these, um, just looking at the initial spreadsheet and the subject matter of these various grants, um, I -- I have real concerns about evenhandedness here.

I have concerns about -- and about health care. I have concerns about black Americans. I have concerns about women. I have concerns about, um, legitimate gender issues having to do with health. But don't any of you take this as prejudging anything. It isn't. It's just the Court's attempt to be fully transparent and to grapple with the issues that the Court is duty-

bound to grapple with.

So -- and for the first round, questions? And we'll start with the plaintiffs, questions on those things? I had not thought of this as an argument session, which is not to foreclose argument, if it's necessary, but I came prepared for scheduling and not argument.

So the plaintiffs, please.

MR. CEDRONE: Good morning, your Honor, Gerard Cedrone for the Massachusetts Attorney General's Office on behalf of the plaintiffs in the states' case. I wanted to raise two issues related to the scheduling on Phase 2 and react to, um, your Honor's statements about the schedule there. The first relates to the question of discovery and the second relates to the schedule more generally.

First, as we previewed here briefly, we do believe that discovery is appropriate on most claims and that they're not properly limited to the administrative record. I don't want to -- if your Honor's not expecting argument today, I don't want to launch into an argument, but we do stress that we think that's appropriate and are happy to brief that or argue that today or at another time, because we do think unreasonable delay claims, unlike claims under Section

7062, the essence of the claim is there is no final agency action, and so unlike --

THE COURT: You're now getting into --

MR. CEDRONE: I'm straying into argument, yes.

THE COURT: But I'm following, and so I think I can make a direct answer.

I'm not surprised by what you're saying. The schedule that now I've tentatively adopted, once we're concluded with the first phase, you can expect they'll move to dismiss. I'll entertain it. I'll rule on it. But we'll assume you survive it. Though I express no opinion. And as part and parcel of that, one imagines I will hear fully the need for extra-record development. And, um, again, that's his last paragraph in the proposal. So we will then, to the extent -- don't think I'm with you here, but we're trying to tease out an intelligent way forward, then we'll talk about the schedule to get at that.

Does that answer your question?

MR. CEDRONE: It does, your Honor. And that leads me to the second question or issue that I wanted to highlight with the schedule. We are concerned that this schedule here, especially for a claim that is grounded in undue-delay risks, moving the resolution of these issues close to the end of the government's fiscal year,

so this contemplates that after Phase 1 is completed, they'll be a week for them to move to dismiss, and then however long that takes to resolve --

THE COURT: You want it faster?

MR. CEDRONE: I do, I think we should walk and chew gum. If they have, you know, a motion to dismiss on those claims, they've had our --

THE COURT: You've got a -- (Laughs.) I think I can walk and chew gum, um, and I don't hear you to suggest otherwise.

What schedule do you suggest?

MR. CEDRONE: No, I'm suggesting that the federal government respectfully should walk and chew gum. We can litigate Phase 1 while I think they file any motion to dismiss that they have, you know, in short order, and produce any administrative record on the second phase in short order. They've had our complaint since April, they've had a --

THE COURT: Well the logic though is that I ought to hear and in my mind react to Phase 1. Now -- you know the truth is, now that we've engaged, I'm going as fast as I can, and when I say, "Well maybe I'll make an order" -- orders get revised in the discipline of writing full opinions. But I, at least conceptually, I'm prepared to take that risk however it comes out.

But, um, maybe I should say that, um, not within 7 days, but if they have a motion to dismiss as to Phase 2, the motion to dismiss must be filed, um, coincident with Phase 1, the 16th?

MR. CEDRONE: We think at least that would be appropriate. And I just want to be clear, I was not suggesting that --

THE COURT: Of course you were not. Of course you were not.

MR. CEDRONE: (Laughs.) We appreciate the dispatch with which this Court acts.

THE COURT: As in any case, we're all here together reaching out for justice. That's my concept of the thing.

So to be fair, I'll modify it. If they want to dismiss, um, the second phase, any motion to dismiss the second phase will be filed no later than -- filed, not entertained on the 16th, but filed no later than the 16th. The rest of it all stands.

Doesn't that make sense?

MR. CEDRONE: I think that would be appropriate. And the other, I think, suggestion we would have is that 30 days --

THE COURT: If I knock that out, or to the extent I deny it, we'll give them 30 days to prepare the

record.

How's that?

MR. CEDRONE: I think that's a bit long, respectfully, your Honor. It's longer than they were given to produce the record for Phase 1.

THE COURT: You said he didn't think -- well actually --

Mr. Ports, you said there wouldn't be much problem in producing the record for Phase 2, would there?

MR. PORTS: I believe I'm not -- I'm not sure what your Honor is referring to. We would request 30 days to file the Phase 2 record, um, as we've requested here. I can also respond to filing it coincident with the hearing on the 16th as well. If we can do that, if that's the Court's order, we believe there would be some benefit from going through the proceeding, hearing the Court's thinking, and having a sense of the resolution, before we file our motion to dismiss on Phase 2, which is why we propose 7 days, which is, we believe, a very short period of time that would allow us to focus on Phase 1 and get it resolved. I understand the Court's thinking, to perhaps get a preliminary ruling, um, get a better understanding of Phase 2 at the time we move to dismiss.

So we do think that there is a benefit to 7 days

or at least some period of days after the 16th.

THE COURT: Okay. How about this? How about this? We'll have the hearing on the 16th. I'll do the best I can, whatever that is. But that's substantive, that will be the findings and rulings. Any motion to dismiss need not be filed on the 16th, but must be filed by the 20th. And then, rather than 30 days, we'll give you until the, um, 9th of July to file the administrative record.

How's that?

MR. PORTS: Thank you, your Honor, we -- that seems to be --

THE COURT: You really --

(Zoom interference.)

MR. PORTS: Yes, your Honor.

THE COURT: Well that's an intelligent and lawyer-like answer.

Now, Mr. Cedrone, I -- I'm trying to be fair. That's acceptable to you?

MR. CEDRONE: Thank you, your Honor. It is.

THE COURT: And I'll again try, um, consistent with other obligations, to address it promptly.

Other questions?

MR. CEDRONE: I don't believe so for the state plaintiffs.

THE COURT: Yeah.

MR. PORTS: For defendants, we just want to clarify that yesterday we received three deposition notices for next week, requests for production and interrogatory responses related to Phase 2, and we just wanted to make clear that the defendants need not respond to these until -- unless and until there's any motion to complete or supplement the record and a ruling on that in Phase 2 from the Court.

THE COURT: I think that makes sense, but then we're not going to be waiting, so you'd better line those people up, and you'd better be thinking about the answers to interrogatories, because I will give a very short time for discovery.

You understand?

MR. PORTS: If the Court orders that discovery is appropriate.

THE COURT: If we get there.

MR. PORTS: Understood, your Honor.

THE COURT: Right. They told you what they want. Be thinking about it.

MR. PORTS: Yes, your Honor.

THE COURT: All right.

Now let's turn to the second case. And my thought is, um, in view of Mr. Ports saying that but-for

individual notices on the specific grants that you have now filed, he doesn't anticipate anything else, can we treat the second case coincident with the first and hear you on the 16th?

MS. AKSELROD: Your Honor, Olga Akselrod with the ACLU on behalf of the APHA plaintiffs.

We are absolutely in favor of consolidating our proceedings with the June 16th hearing and believe that, um, the record as to the directives, um, may well decide many many of the issues in this case. But there is a difference in terms of the record that has been produced in the states' case and the record that has been produced in our case.

As you know, in the states' case the individual termination ARs have been produced, and those are set to be produced, um, by the defendants on June 16th in our case.

We have, um, proposed that the parties meet and confer on June 5th, um, which would give us enough time to review what has been, um -- what has been provided as to the ARs in the states' case. The defendants have proposed potential stipulations that may obviate the need for, um, submitting the individual terminations AR in our case, and we just need the parties to have a little more time for us to review the record, um, and

also to figure out whether such stipulations would be sufficient.

THE COURT: All right. Yeah, look, I gave them day for day what I gave the states from your start time.

MS. AKSELROD: Yes, your Honor.

THE COURT: I'm not -- I'm not going to revise that. I did that having thought it through. Having said that, there is so much to be gained by agreement. And I urge -- but I am not ordering, and I'm not setting interim dates, further agreement.

I hear you say that you will -- however it works out, if you don't agree, you want to be heard and argue as to these directives, and, to the extent you can legally, you want to argue as to, um, grant terminations in your case on the 16th.

Right?

MS. AKSELROD: Yes, your Honor.

THE COURT: And I propose, in that 3 hours, to hear you. And I propose -- I intend to hold myself ready for argument in -- I'm calling it the "second case," but only that's because it -- how it emerged into my consciousness. It's not "second" in any way and I've spoken to it on an individual basis.

So I'm simply going to hold you to that. We'll do the first phase and then we'll see where we are.

MS. AKSELROD: Thank you, your Honor.

And we would propose that on June 6th, we would be able to provide the Court with a status report as to the parties' discussions and what if any additional ARs may need to be produced, and a proposed sort of supplemental, um, schedule for how to deal with those.

THE COURT: Well you're looking for a court order. You can file anything you want.

I do enjoy meeting with you all. Really that's not a personal thing, there's much to be said for the management and the joint efforts that everyone is putting into these two cases. At the same time, I'm not big on status conferences.

So you file what you want. I'll do -- I won't say "what I want," but I will enter a due-appropriate order or no order. I have the case now entrained for argument on the 16th. I've got a lot of stuff to look at. I suggested other things I want to look at and I do want to look at them. And I have legal work to do. And I intend to give you a full and fair hearing on the 16th.

If I hear no other questions, I think we can --

MS. AKSELROD: Your Honor, I do have a few more questions.

THE COURT: Yes, go right ahead.

MS. AKSELROD: So -- well, first of all, I just

wanted to raise that the parties, um, did have some additional discussions over the course of the last two days on some modification to the schedule that was, um, proposed by the states and the defendants in that case. And I understand your Honor has adopted that schedule. We think that that schedule also makes a lot of sense in virtually every way. But the parties have agreed to a couple of modifications.

THE COURT: If you agree to them, put them in writing and let me know.

MS. AKSELROD: Perfect. Thank you, your Honor.

Secondly, um, I just wanted to clarify. So, first of all, of course to the extent that the parties are not able to reach stipulations, um, by June 5th, we would be arguing based on the directives AR, um, and wouldn't have the benefit of being able to make argument with regards to the grant termination AR, which we're not receiving until June 16th. So I just wanted to clarify that we will be prepared to argue as to the directives AR. We believe that the grant terminations can be resolved through the directives AR. If the Court finds that is unlawful, then relief would flow to those. But we just wanted to be clear that there may be a limitation as to what we argue.

THE COURT: You're making yourself clear.

MS. AKSELROD: Perfect. Thank you, your Honor.

And one, um, other clarification that I just wanted to raise with regard to the scope of Phase 2, um, and this is one of the ways that our case differs a little bit with regard to how I think this Court has framed Phase 2, which so far has been about unreasonable delay and 7061. And I just wanted to raise that in addition to 7061 claims, the APHA plaintiffs have also brought 7062 claims on behalf of the applicant.

THE COURT: I understand. I've ruled on -- I've treated their argument as a motion to dismiss and I've ruled on it. Believe me, I understand what your complaint raises.

MS. AKSELROD: Yes, your Honor, thank you. And that is of course also a difference in the schedule since, um, the motion to dismiss, as you've just noted, has already been heard in our case.

I just wanted to also raise that, from our perspective, the June 16th hearing as to the directives, um, could give relief not only as to the grant terminations, but also as to the suspension of applicant processes based on the directives.

THE COURT: I will tell you, in all candor, I had not thought of that. Now you may be arguing that, but I'm trying to get my hands around this case, and, um,

while relief as to people actually -- as to grants actually terminated is potential, that's why I wanted the list. So -- and that will be the Court's focus.

Obviously it's your complaint and you raise any claim you wish. I've ruled on a motion to dismiss. It's my duty to adjudicate the claims. Um, but that's my response.

I think I'm -- the public officials are wrong to say we're only going to talk about the grant terminations, not these directives. I want to know all about these directives. I want to know where they came from. I want to know why there were no edits. And this business, which is fulsomely set forth in your complaint, we'll hear at least all about that. I want a full record as to those directives. And then I want to see how it plays out in cutting off funding for grants approved. That's what I thought we were talking about.

Now I guess all I can say is that's the Court's focus and it will be the Court's focus on the 16th. You can feel free to raise anything that the complaint raises. But when we talk about potential orders and the like, um, I'm limiting it to these plaintiffs, these grant -- Phase 1, these grant terminations. Now there is a Phase 2. I'm not expressing any opinion on that.

Is that helpful?

MS. AKSELROD: Yes, your Honor, it is. I think we may, um, with the Court's permission, still spend a bit of time explaining how the directives expressly require an applicant --

THE COURT: You will, on the 16th, and you will not think that I am, um, prejudging it if you spend that little time towards the end.

MS. AKSELROD: Thank you, your Honor.

THE COURT: All right.

Any other questions?

And again, hope springs eternal. If you resolve this matter or a significant portion of it, a simple call to Ms. Belmont is all that's necessary.

Yes, Mr. Ports?

MR. PORTS: Yes, your Honor. Thank you.

I wanted to clarify regarding the supplementing of guidance about what is contained in the administrative record.

Although it is the defendants' position that the grant terminations should be reviewed, the administrative record contains well-challenged directives, um, the -- where the challenged directives were considered, directly or indirectly, in the grant terminations, they're a part of that administrative record. Where they were not, we have provided separate

administrative records for the other, um, challenged directives, to the extent we have had record IDs.

THE COURT: You'll appreciate that I haven't reviewed it, and so if I've misspoken, it's solely because I have not yet had the chance to review it all.

All right.

MR. CEDRONE: Your Honor --

THE COURT: I have another obligation here.

MR. CEDRONE: I just want to clarify what was just established, which is that, um, having heard your Honor's views and admonitions, that the administrative record in the states' case is complete, um, in the government's view.

THE COURT: He said it was.

MR. CEDRONE: Okay, I just wanted to make sure of that.

THE COURT: While I'm operating -- we talk about "clarifications," um, the question is, um, that "clarifications" all, respectfully, have to go to me. I'm telling you what I think Mr. Ports has represented, that I have a complete administrative record as to the, um, challenged declarations. That's what I heard him say. And that -- well I'll stop there.

MR. CEDRONE: Thank you, your Honor.

THE COURT: Lest I clarify my own clarifications.

Thank you all.

We'll stand in recess.

(Ends, 11:45 a.m.)

C E R T I F I C A T E

I, RICHARD H. ROMANOW, OFFICIAL COURT REPORTER, do hereby certify that the forgoing transcript of the record is a true and accurate transcription of my stenographic notes, before Judge William G. Young, on Tuesday, June 2, 2025, to the best of my skill and ability.

/s/ Richard H. Romanow 06-05-25

_____

RICHARD H. ROMANOW Date

Nos. 25-1611, 25-1612

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; NICOLE MAPHIS,

Plaintiffs-Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in the official capacity as Secretary of the United States Department of Health & Human Services,

Defendants-Appellants.

COMMONWEALTH OF MASSACHUSETTS; STATE OF CALIFORNIA; STATE OF MARYLAND; STATE OF WASHINGTON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF DELAWARE; STATE OF HAWAII; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF WISCONSIN,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., in the official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; NATIONAL CANCER INSTITUTE; NATIONAL EYE INSTITUTE; NATIONAL HEART LUNG AND BLOOD INSTITUTE; NATIONAL HUMAN GENOME RESEARCH INSTITUTE; NATIONAL INSTITUTE ON AGING; NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM; NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING; EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION

DISORDERS; NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH; NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; NATIONAL INSTITUTE OF MENTAL HEALTH; NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES; NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE; NATIONAL INSTITUTE OF NURSING RESEARCH; NATIONAL LIBRARY OF MEDICINE; NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES; JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES; NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH; NIH CENTER FOR SCIENTIFIC REVIEW,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Massachusetts

APPENDIX - VOLUME II

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF BRITTANY CHARLTON

I, Brittany Charlton, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. My name is Brittany Charlton. I am an Associate Professor at Harvard Medical School and the Harvard T.H. Chan School of Public Health and Founding Director of the LGBTQ Health Center of Excellence. As an internationally recognized expert in lesbian, gay, bisexual, transgender, and queer (LGBTQ) health, particularly cancer and reproductive health outcomes, I have focused my career on producing data-driven research to inform clinical practice and public policy.

2. I am offering this declaration in my individual capacity and not on behalf of my employer.

3. I was raised in a family of proud union nurses who believed deeply in service, fairness, and standing up for those in need. Therefore, I was called to public health through years of academic work, advocacy, and frontline healthcare within LGBTQ communities. For example, I proudly served a year in AmeriCorps at an LGBTQ-focused community health center, providing HIV counseling and cancer screenings, training physicians in respectful, evidence-based care, and supporting LGBTQ teen moms as a birth doula. I then earned my MSc and ScD in epidemiology from the Harvard T.H. Chan School of Public Health.

4. Before age thirty, Harvard Medical School and the Harvard Chan School of Public Health recruited me to their faculties. I have published over 100 research papers in top medical journals, including *The Journal of the American Medical Association (JAMA), The BMJ*, and the *American*

Journal of Preventive Medicine. My work has been cited over 2,600 times. I have mentored over seventy-five faculty, postdoctoral fellows, and trainees, earning international recognition for my commitment to developing the next generation of scientists. A year ago, I launched the LGBTQ Health Center of Excellence—an initiative to advance health equity through an academic center that trains future leaders, drives innovative research, and informs public policy.

5. With a proven ability to win and manage federal grants, I was prepared to secure the funding needed to establish a lasting academic center. Over the past fifteen years, I have received continuous National Institutes of Health (NIH) funding, securing more than fifteen grants. I was awarded a large-scale R01 grant early in my career, an uncommon achievement. NIH grant applications are incredibly demanding. Preparing one can take months or even years and involves entire teams of scientists and staff. Proposals often exceed 200 pages and must make a compelling case that the health issue being studied is urgent and nationally significant. Applicants must prove that their proposed methods are the best possible approach to solve the problem. They must also demonstrate that their team is uniquely qualified. Every application undergoes rigorous peer review by experts, and funding rates are low—especially for R01 grants, where many researchers apply multiple times before ever being funded. Securing a grant is not just about money—it is a hard-won endorsement of a project's scientific importance, methodological rigor, and real-world potential to improve public health.

6. Since March 2025, NIH has terminated my entire portfolio of grants; I was the sole principal investigator for three of these grants and co-investigator of two others. For each grant, NIH stated in a termination notice that the project "no longer effectuates agency priorities." The total NIH funding allocated in those five multi-year grants was approximately $16 million; the early terminations resulted in roughly $6 million in lost funding as the projects were still underway. To put this loss in perspective, I rank as the fifty-first most highly funded NIH investigator compared to the nearly 500 faculty across Harvard's thirteen schools (e.g., Harvard College, Harvard Medical School, Harvard Chan School of Public Health). Terminating my entire portfolio has been no minor adjustment, but rather the abrupt defunding of one of the most federally supported research programs in LGBTQ health in the world.

7. One of these terminated grants was an "R61" grant (R61HD117134), aimed at time-sensitive policy questions, to study the impact of discriminatory and supportive legislation on the mental health of LGBTQ young people. NIH reviewers scored the grant application in the top

twelfth percentile, and it was approved for $4.15 million in costs over five years; it should have received an automatic no-cost extension for a sixth year.

8. A true and correct copy of this R61 grant's Notice of Award (i.e., NOA) is attached as Exhibit A.

9. The overarching goal of the R61 project was to understand how four types of LGBTQ-related policies—religious exemptions, healthcare bans, restrictive curricula, and supportive curricula—impact mental health in late adolescence and early adulthood. The findings would offer timely, evidence-based guidance to help healthcare providers, educators, and policymakers improve mental health for all young people, not just those who are LGBTQ.

10. To complete the project's research aims, our team collected time-sensitive data from the Healthy Minds Study—the largest mental health survey of U.S. college students. We used these data to examine how policies and stigma are linked to mental health, with results disaggregated for LGBTQ and non-LGBTQ students. We then conducted in-depth interviews with individuals directly impacted by these policies. Next, we used nationally representative Behavioral Risk Factor Surveillance System data to estimate the effects of supportive and discriminatory policies among the entire U.S. population. In future years, we were going to apply quasi-experimental methods to quantify the causal impact of such policies on mental health.

11. Over a quarter of U.S. young adults identify as LGBTQ and face disproportionate rates of depression, anxiety, and suicide compared to their peers. The wave of state policies targeting LGBTQ people continues to grow—more than 500 such bills were proposed in state legislatures in 2024 alone. This study was built on my prior research on mental health disparities that arise from such structural stigma and discrimination. We aimed to guide urgently needed interventions that improve mental health and help vulnerable, underserved communities—goals squarely aligned with NIH's stated priorities.

12. Applying for the R61 grant was an intense and compressed process. The funding opportunity, not to mention the research, was time-sensitive. We had only months to write the application to secure five years of funding. The process demanded deep expertise, coordination with collaborators across the U.S., and attention to detail to meet NIH's rigorous standards. I had to set aside personal milestones like family events, celebrations, and other professional obligations to develop a competitive application under significant time pressure. The research topic was meaningful to me and the broader LGBTQ community, of which I am a member; therefore, I felt

the sacrifice was worthwhile at the time. A true and correct copy of a printout of the R61 funding announcement, accessed April 18, 2025, is attached as Exhibit B.

13. The funded project launched on August 26, 2024. Before the termination, I had never received any previous indication that my grant was in jeopardy.

14. The R61 grant supported about a third of my time.

15. Less than eight months into the five-year project, NIH issued a termination notice on March 12, 2025, stating that the award "no longer effectuates agency priorities." A true and correct copy of the R61 termination notice is attached as Exhibit C.

16. Two days later, on March 14, 2025, I received a revised Notice of Award reflecting the R61 grant's termination and echoing the termination letter's language. A true and correct copy of the revised Notice of Award is attached as Exhibit D.

17. Neither the revised Notice of Award nor the termination notice included any individualized explanation for why NIH cancelled the grant, and both failed to discuss the grant application, progress reports, or other related materials (despite the project's exceptional documented productivity, including advancement ahead of proposed timelines, publication of results, and ongoing dissemination efforts). Instead, the termination notice stated:

> This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research program. [*sic*]

Ex. C at 1; *see also* Ex. D at 5.

18. I do not understand what the termination notice and revised Notice of Award mean by "gender identity" or "biological realities" concerning my project. When I reached out to my NIH Program Officer—the PhD-level scientific staff member responsible for overseeing and supporting funded research projects—she confirmed that she was not consulted about the termination of my grant. She also stated that she had never witnessed such terminations in her nine years at the agency. She expressed that the process surrounding my grant's termination was highly unusual. She explained that the National Institute of Child Health and Human Development ("NICHD") scientific staff typically oversee and manage grants. But, in this case, they were given no information about how awards were selected for termination, what criteria were used, or who made the decisions. She emphasized that program staff like her were not even notified of the termination until the revised Notice of Award was issued following the termination letter, describing this

sequence as far outside the norm. This Program Officer expressed that she did not understand how anonymous decision-makers not familiar with the details of the project had concluded that "no corrective action is possible" or that the project conflicted with agency priorities—particularly as I had responded to a specific Notice of Funding Opportunity that sought out projects addressing this particular topic. She also stated that, if given a chance to appeal, she believed our team could propose feasible modifications, emphasizing that the project was not focused on "gender identity" but rather on the health effects of policies related to sex and gender.

19. As a mid-career researcher familiar with NIH processes and norms, I know that early termination under these circumstances is highly unusual and inconsistent with established precedent. It is extremely rare for a grant to be terminated mid-project, I have only ever seen this happen when an investigator has engaged in misconduct or a research participant (e.g., patient) has been harmed.

20. What is happening now with NIH grant terminations is markedly different: research participants are being put at risk because NIH has abruptly withdrawn support. For example, in the case of a randomized controlled trial, this support is being withdrawn partway through their treatment, allowing for no oversight of the close-out process. It has taken over a month of daily meetings, including with institutional leadership and staff, as we tried to make sense of the termination and to formulate a plan for how to responsibly close out the project while safeguarding the health and well-being of the study participants. Closing out a large study—especially midstream—requires tremendous effort: reviewing protocols, contacting participants, and protecting data integrity. The lack of an orderly process could result in real harm, and my research team is struggling without guidance to safeguard study participants.

21. At the time NIH terminated the R61 grant, my team was actively conducting sensitive, in-depth interviews with young people across the U.S. whose mental health was directly impacted by discriminatory and supportive legislation. Participants were sharing intensely personal stories about the toll of living under policies such as "Don't Say Gay" laws—stories they may not feel safe disclosing again. We were forced to cancel multiple interviews scheduled for the next day, without explanation. This sudden disruption jeopardized the emotional well-being of already vulnerable young people and raised serious ethical concerns. Such abrupt cancellations risk increasing distress among participants who were already actively struggling with their mental health. The termination shattered a real-time study to document a rapidly evolving public health crisis. As a result, we risk losing valuable firsthand accounts during a pivotal period. The loss

would constitute a blind spot in the scientific record and a missed opportunity to inform urgently needed health and policy interventions.

22. I had also received an R01 grant (R01MD015256) awarded to my institution, titled *Sexual orientation-related disparities in obstetrical and perinatal health*. A true and correct copy of the Notice of Award for this R01 grant is attached as Exhibit E. The project was a "longitudinal study" following a population over time. We designed the study to quantify obstetrical and perinatal health disparities between lesbian/bisexual women and their heterosexual peers (notably, the study did not include transgender participants). Lesbian/bisexual women and their children account for an estimated 800,000 births annually across the country. Prior research found that LGBTQ women have more risk factors (e.g., depression, substance use) for adverse obstetrical and perinatal outcomes compared to heterosexual women. The hypothesis that this study was designed to test was that lesbian and bisexual mothers are subjected to unique forms of stigma, prejudice, and discrimination. Therefore, this research filled a gap in our understanding; little is known about how pregnancy outcomes—not to mention the baby's health—differ across sexual orientation groups. Studying groups, like lesbian/bisexual women, that experience disproportionately high rates of adverse outcomes allows scientists to identify risk factors. Our preliminary research has revealed that lesbian/bisexual women have higher rates of adverse pregnancy outcomes than their heterosexual peers, making their inclusion essential.

23. In 2020, NIH reviewers scored the grant application in the top seventh percentile, and the project was approved for $4.42 million in funding over five years; it should have received an automatic no-cost extension for a sixth year.

24. The research took advantage of three unique, ongoing longitudinal, intergenerational cohorts: the Nurses' Health Study 2, their offspring in the Growing Up Today Study 1 and 2, and a third generation of the Growing Up Today Study participants' children. Our team analyzed obstetrical and perinatal inequities across sexual orientation subgroups, using advanced study designs that allow for intergenerational comparisons. Finally, drawing on well-established research linking chronic stress from discrimination to health outcomes, we examined factors like depression, substance use, and social support to understand what drives health inequities—and where targeted interventions could make the greatest impact.

25. By generating rigorous evidence about research participants' health needs—including those of lesbian/bisexual women and their heterosexual peers—the study directly supported NIH's stated goal of identifying and addressing the needs of at-risk populations. Improving the health of

lesbian/bisexual women and their children addresses other major NIH priority areas, such as understanding the mechanisms of inequities. Most importantly, this study was designed to identify targeted interventions that would improve the health of lesbian/bisexual mothers and their children.

26. Applying for the R01 grant was an extraordinarily time-intensive process. I wrote and revised this grant application multiple times, supported by a team of staff, trainees, and collaborators. I applied twice, subjecting the project to rigorous peer review. Securing an R01 grant is widely recognized as a career-defining achievement in biomedical research, with success rates in the single digits and a typical age of first award in the mid-forties.

27. Receiving my grant at age thirty-five was a tremendous honor and turning point in my career. This grant allowed me to hire and retain staff, as well as support myself and my family.

28. Over 50 of my mentees were involved with this project, including faculty, postdoctoral fellows, doctoral degree students, master's degree students, and staff. In 2024 alone, the team published fifteen peer-reviewed scientific papers on various sexual orientation-related health inequities, and we presented the project's conclusions forty-three other times at scientific meetings.

29. The R01 grant supported almost fifty percent of my time.

30. This study was so successful that NIH continued funding this grant for four years; at no point was there any indication that the grant was in jeopardy.

31. Four years into the five-year grant, on February 18, 2025, my institution received a revised Notice of Award reflecting a no-cost two-month extension of the previous year's award until April 30, 2025. I found this highly unusual as no-cost extensions are almost universally granted after the originally funded period for a research grant concludes (at the end of year 5 for a typical R01) to allow remaining work to be completed, and only at the investigator's request. There was little to no context on this unusually limited extension. While my institution planned to contact our NIH-assigned Grants Management Specialist, I proactively contacted my NIH-assigned Program Officer for context; I received no response. I also contacted the Program Officer's supervisor—a Division Director at the National Institute on Minority Health and Health Disparities ("NIMHD")—and received no response.

32. That revised Notice of Award for this R01 grant was the last communication that I have received regarding this grant; a true and correct copy of this latest R01 Notice of Award in PDF form is attached as Exhibit F.

33. On March 21, 2025, my institution forwarded me a notice from NIH terminating the grant stating that the award "no longer effectuates agency priorities." A true and correct copy of the termination letter is attached as Exhibit G. I have redacted my personal email address from the attached exhibit solely to protect my personal identifying information.

34. The termination notice does not include any individualized explanation for why the grant was cancelled. It does not identify any places where we failed to meet any objectives or goals, cites no areas of poor-quality work or scientific misconduct, and fails to discuss any of the data or analysis from our application, annual progress reports, or other related material. Instead, the termination notice includes the following language about its decision:

> This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Ex. G at 1.

35. I do not understand what the notice means by the phrase "diversity, equity, and inclusion ('DEI') studies," and I do not know why NIH believes this project is based on "amorphous equity objectives." While the project did involve lesbian and bisexual participants, the research focused on studying and developing interventions to improve maternal and perinatal health outcomes for all mothers, including heterosexual women. The only imaginable "equity objective" was that we were trying to improve healthcare for a segment of the population that had been largely ignored despite a greater-than-average rate of poor outcomes. Like any NIH-funded project, our application was required to have very clear objectives, based on established scientific literature.

36. I also do not understand why NIH claims this project does not effectuate agency priorities. In October 2016, after a rigorous, evidence-based review process, NIH officially designated LGBTQ populations (i.e., "sexual and gender minorities") as a health disparity population—a designation reserved for groups facing significant, documented health disparities. This designation made research on LGBTQ health an explicit NIH priority, reinforcing the importance of studies like mine in addressing national public health needs. A true and correct copy of a printout of the NIH webpage detailing this policy, accessed April 18, 2025, is attached as Exhibit H. I developed this project in part because it was directly aligned with NIH's stated research priorities at the time and responded to explicit calls for work in this area.

37. As outlined above, terminating my R01 grant under these circumstances is a stark departure from established NIH norms and precedent.

38. This project supported an entire research team, many of whom built their careers on the work it enabled. For me, this research represented over two decades of dedication to addressing reproductive health inequities in LGBTQ populations—an area of study that has historically been ignored. The grant allowed dozens of students and trainees to publish papers, gain clinical insight, and pursue careers in medicine and public health.

39. Further benefits from this project are now at risk. Critical findings, such as data showing that lesbians are nearly three times as likely to experience stillbirth as heterosexual women, may never be published—a waste of the taxpayer dollars that funded years of prior research. Without the support from this grant, the trainees leading the study no longer have the salary support or institutional backing to complete data analysis and manuscript preparation. They face serious career setbacks, job insecurity, and financial instability, and they cannot finish their work. They may have no peer-reviewed publications, no tangible outcomes from their pre- and postdoctoral training, and significantly reduced chances of securing future funding or jobs. This means the research will sit unfinished, and its potential to save lives will be lost. This is not just an academic loss—it means more patients will suffer harm, more pregnancies will end in preventable stillbirths, and systemic inequities will remain unaddressed.

40. Tied to my R01 grant was an administrative supplement grant (R01MD015256) of approximately $100,000, titled *Improving service delivery models of medically assisted reproduction: A patient journey mapping study of sexual minority women couples' experience of medicalized family formation*. This award was to support an advanced postdoctoral fellow on our research team. This grant would have enabled her to have the necessary final year of postdoctoral training before moving into a faculty role, providing a sound footing for her future career. This opportunity is now lost to her. A true and correct copy of the R01 administrative supplement grant's Notice of Award is attached as Exhibit I.

41. The supplemental grant project was designed to study how LGBTQ couples form families. It recognized the specialized fertility services they may require and the negative experiences they may encounter in accessing fertility care. The overall goal was to help other LGBTQ couples seeking to start a family.

42. Our research team conducted semi-structured interviews with LGBTQ couples trying to become pregnant, capturing in-depth qualitative data on their fertility care. These data were paired

with quantitative assessments, such as measures of mental health and healthcare history, for a robust, mixed-methods analysis.

43. To provide an intuitive understanding of LGBTQ patients seeking fertility care, we planned to use a human-centered research method known as journey mapping. It visually charts how an individual interacts with a system—such as reproductive healthcare—to identify key barriers and facilitators in their experience. A central aim of the study was to translate this data into actionable insights for fertility clinics. The project aimed to increase providers' awareness and empathy of the distinctive burdens faced by women in same-sex couples navigating fertility care, with the goal of improving clinical practices and patient experiences. The study was also designed to develop best practices for inclusive data collection in national cohort studies, laying the groundwork for future large-scale research on preconception and perinatal health inequities.

44. This project directly addressed the core objectives outlined in the NIH Sexual and Gender Minority Research Office's funding announcement (i.e., Notice of Special Interest), which solicited administrative supplements to expand existing research projects to incorporate LGBTQ populations or LGBTQ-relevant research questions. The funding announcement explicitly prioritized research in high-need areas identified through NIH's own portfolio analysis. The project's aims were fully aligned with NIH's stated scientific and policy goals—namely, to ensure the inclusion of LGBTQ populations in rigorous, data-driven studies. A true and correct copy of a printout of the Notice of Special Interest webpage, accessed April 18, 2025, is attached as Exhibit J.

45. Applying for the R01 administrative supplement was an enormous undertaking, despite the relatively small funding amount. As a mid-career investigator, I typically would not write a grant for $100,000 due to the high time and resource demands—it requires support from a whole team of staff and scientists. I donated significant staff and personal time to pursue this supplement to support an exceptional trainee with a compelling idea and no other funding source. We collaborated closely on the submission because this award would allow her to extend her postdoctoral training and pursue promising research that could serve as a springboard for her future career.

46. On March 21, 2025, before the project could fully get off the ground, my institution forwarded me a notice from NIH terminating the grant stating that the award "no longer effectuates agency priorities." A true and correct copy of my termination notice is attached as Exhibit K. I

have redacted my personal email address from the attached exhibit solely to protect my personal identifying information.

47. There was no reference to the scientific merits of the proposal, the project's aims, or any materials submitted in our application. Instead, the termination notice relied solely on generalized language, offering no substantive explanation or evidence-based rationale for the decision. The termination notice stated:

> This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Ex. K at 1.

48. As above, I was never given any previous indication that this grant was in jeopardy, and termination under these circumstances is highly unusual and inconsistent with NIH precedent.

49. As with the termination notices for the grants described above, I do not understand why NIH believes this project is based on "gender identity." The project's primary focus is on women in same-sex couples trying to become parents. I also do not understand what the notice means by "biological realities." The project was open to any participants who could become pregnant (potentially including transgender participants, though the project did not progress far into the phase of participant recruitment). We focused on how LGBTQ women form families and the ways these women may receive different or substandard obstetrical and gynecological care that could put their health at risk or interfere with their ability to form families. I also do not understand why NIH believes this project does not effectuate agency priorities, as agency guidance indicated that research concerning LGBTQ people was an NIH priority.

Ex. H.

50. This grant's termination has effectively derailed the career trajectory of a talented postdoctoral fellow who is not only a member of the LGBTQ community but also poised to become a future leader in this field. She turned down other career opportunities to commit to this project. The grant's termination abruptly eliminated her salary support and prevented the research from fully launching; at this point, the timeline has passed, and the opportunity is lost. This fellow's success would have advanced research into health disparities and positioned me to mentor another

postdoctoral fellow through a successful faculty transition—mentorship that would have been an additional benefit to me to advance my career from Associate Professor to Professor.

51. Because of the loss of my entire portfolio of grants, I have lost nearly all my salary and the money to pay the wages of about eighteen people in my organization who directly or indirectly support these research studies. I have already had to terminate a senior team member and fear I will have to terminate all remaining team members. Faculty and staff based at our study's subsites (i.e., Boston Children's Hospital, Harvard T.H. Chan School of Public Health, Brigham and Women's Hospital, University of Utah, Boston University) have lost salary support or had their employment terminated.

52. The termination of this research has upended the lives and careers of dozens of my team members—master's students, doctoral students, postdoctoral fellows, faculty, and staff, many of whom relocated or made life-altering commitments to pursue this work. One student has taken medical leave for mental health reasons following our grant terminations and may never return to the field. Another team member—this one more senior in their career—is also on leave, partly due to the stress this upheaval has caused. Some of the brightest scientists in public health and medicine are now being aggressively recruited to academic institutions outside the U.S. Others are leaving academic research and teaching careers entirely. Several have begun rewriting their CVs to downplay their LGBTQ identities or erase the focus of their health equity work, no longer confident that this scholarship is safe or valued. One of our team's senior members confided: "The threats to our work don't just make me fear for my career—they make me fear for my safety. I wonder whether this country still has a place for people like me." These grant terminations are not just the loss of individual careers—it is the quiet dismantling of a generation of future leaders in medicine and public health, and with them, the hope for a more equitable future.

53. Worse still, the breach of trust with our research participants will be exceedingly hard to repair. Many of them entrusted us with highly sensitive information about their lives, and the sudden termination of this grant has made it clear that their contributions were not treated with the seriousness they deserved. Even if funding were restored today, I am not sure these participants would—or should—trust us again.

54. When time-sensitive or long-term studies are cut short, the consequences are lasting. Data becomes unusable, follow-up is lost, and the study's design collapses, undermining current findings and future research. In this case, the termination severed a rare and irreplaceable source of insight into an underserved population. Scientific progress depends on continuity; repairing the

damage once that chain is broken is difficult. As importantly, it is an ethical breach: participants entrusted us with intimate details of their lives, believing their stories would be used for the public good.

55. Scientists who conduct human subjects research are required to complete a course in ethical principles and individual protection. This training is grounded in the Belmont Report, a foundational document that outlines core principles for protecting research subjects: respect for persons, beneficence, and justice. It was developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1978. It serves as the basis for many current research regulations, all of which scientists are mandated to follow. Funding terminations without cause and with no plans or guidance for protecting research subjects have created, at the very least, an ethical breach that cannot be easily repaired.

56. The loss of my entire grant portfolio has crippled the LGBTQ Health Center of Excellence, marking the end of much of Harvard's LGBTQ health research. It is personally and professionally devastating to see the closure of our academic center, which I spent much of my career developing. Worse still, it sends a chilling message to others in the field that research serving marginalized communities is no longer safe or sustainable. This threatens the future of public health and evidence-based medicine. It also puts many individuals at potential risk—including those who are racial/ethnic minorities, low-income, or disabled—without acknowledging their right to health.

57. Following the termination of these grants, the personal toll of standing up for this work has been as devastating—if not more so—as the professional consequences. Since I began speaking out publicly about the importance of safeguarding research into LGBTQ health—before any of my own grants were affected—I have been met with an onslaught of hostility. The harassment has escalated rapidly, invading both my digital life and my private office. I've faced waves of online abuse filled with hate and fear — and disturbingly, threats have arrived at my doorstep, forcing me to tighten home security.

58. These grant terminations have broader implications. When science is silenced by ideology, we all lose. If research on marginalized communities can be erased for political reasons, it sets a dangerous precedent: that some lives are less worthy of understanding, care, or protection. This is not just an attack on the LGBTQ community—it is a blow to the integrity of science and the health of every American.

59. I am actively appealing these terminations, but am at a loss for how to do so. The language used to justify the terminations is vague, making it impossible to understand why this work was

deemed unacceptable or what corrective action one could reasonably take to address any perceived substantive issues. I cannot ethically or responsibly recharacterize my project to meet priorities that have not been clearly defined. I have had to close out work that involves at-risk populations without guidance in an area where the stakes are far too high for guesswork.

60. As I continue to manage closing out these projects, I am aware that success may be impossible: The termination notices assert that the research's premise is fundamentally incompatible with the agency's new priorities, and therefore, truth seems to have become subordinate to ideology—a shift that threatens not just science but the very foundations of democratic inquiry.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 23rd day of April, 2025.

Brittany Charlton

Brittany Charlton

EXHIBIT A

Case: 25-1611 Case: 1:25-cv-10787-IT Document: 70-1 Filed: 04/25/2025 Page: 3519 Date Filed: 04/25/2025 Page 18 of 97 Entry ID: 6736790

Recipient Information

1. Recipient Name
HARVARD PILGRIM HEALTH CARE INC
1 WELLNESS WAY
CANTON, MA 02021

2. Congressional District of Recipient
08

3. Payment System Identifier (ID)
1042452600A1

4. Employer Identification Number (EIN)
042452600

5. Data Universal Numbering System (DUNS)
071721088

6. Recipient's Unique Entity Identifier
NZVVQ8GNVX65

7. Project Director or Principal Investigator
Brittany Michelle Charlton, DSC
Assistant Professor
bcharlton@mail.harvard.edu
617-466-9262

8. Authorized Official
Cary Williams

Federal Agency Information

9. Awarding Agency Contact Information
Yvonne C. Talley
Grants Management Official
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
talleyy@mail.nih.gov
301-496-7432

10. Program Official Contact Information
Ronna Popkin

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ronna.popkin@nih.gov
301-827-5121

Federal Award Information

11. Award Number
1R61HD117134-01

12. Unique Federal Award Identification Number (FAIN)
R61HD117134

13. Statutory Authority
42 USC 241 42 CFR PART 52

14. Federal Award Project Title
Supportive and restrictive factors and mental health in LGBT adolescent and young adult populations

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/26/2024 **– End Date** 07/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$838,837
20 a. Direct Cost Amount	$694,515
20 b. Indirect Cost Amount	$144,322
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$838,837
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$838,837
26. Project Period Start Date 08/26/2024 **– End Date** 07/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$838,837

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Yvonne C. Talley

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Version:25 - 2/15/2024 9:51 AM | Generated on: 8/26/2024 12:12 AM

A0784

Notice of Award

Phase 1 Exploratory/Developmental Grant
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1R61HD117134-01

Principal Investigator(s):
Brittany Michelle Charlton, DSC

Award e-mailed to: research_admin@harvardpilgrim.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $838,837 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to HARVARD PILGRIM HEALTH CARE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R61HD117134. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Yvonne C. Talley
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$140,347
Fringe Benefits	$41,823
Personnel Costs (Subtotal)	$182,170
Consultant Services	$5,000
Travel	$6,500
Subawards/Consortium/Contractual Costs	$500,845
Federal Direct Costs	$694,515
Federal F&A Costs	$144,322
Approved Budget	$838,837
Total Amount of Federal Funds Authorized (Federal Share)	$838,837
TOTAL FEDERAL AWARD AMOUNT	$838,837
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$838,837

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$838,837	$838,837

Fiscal Information:
Payment System Identifier: 1042452600A1
Document Number: RHD117134A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
OD	8055729	$838,837

NIH Administrative Data:
PCC: PDB -RP / **OC**: 41021 / **Released**: 08/15/2024
Award Processed: 08/26/2024 12:12:01 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R61HD117134-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R61HD117134-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-

research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R61HD117134. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Office Of The Director, National Institutes Of Health (OD)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1R61HD117134-01

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

TRANSITION PHASE

In accordance with **PAR-22-233**, funding for the **R33** phase of this award will be is contingent upon (1) determination that the **R61** goals and milestones were achieved; (2) review and approval of the transition application package; and (3) availability of funds.

The following documentation/information must be provided in the **R33** transition application:

1. Detailed categorical budget and justification for each year of the **R33** phase. Total direct costs cannot exceed the competing application requested amounts or the Integrated Review Group recommended funding levels, if applicable.
2. Milestones section identifying the approved **R61** milestones and the progress towards meetings those milestones.
3. One-page abstract describing the **R3** phase research plan. State if the originally approved aims have been modified or remain the same. If modified, provide a justification for the modifications.

These components are required two months prior to the anticipated start of the **R33** phase. The report should be sent as a single pdf attachment to the Grants Management Specialist and Program Official indicated on this Notice of Award using the PHS 2590 format. The report must be approved by the institutional Signing Official.

The appropriate NICHD Grants Management and Program staff will review the **R33** transition application. If the transition request is not approved, written notification will be sent to the applicant.

****

Co-fund
This award provides co-funding support in the amount of $838,837 ($694,515 direct costs + $144,322 facilities and administrative costs) from Office of Behavioral and Social Sciences Research (OBSSR).

Start Date
This award includes funds for twelve months of support but is awarded for less than twelve months.

Human Subjects
For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

Data Management Sharing Plan
Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the **application** dated **02/14/2024.**.

Graduate Student
The maximum amount that NIH will provide to support the compensation package (salary, fringe benefits and tuition remission) for a graduate student is equal to the zero

level postdoctoral stipend in effect at the time of the completing award, as described in NOT-OD-02-017. This award has been adjusted accordingly.

Consortium

This award includes funds awarded for consortium activity with Boston University.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R61HD117134-01

INSTITUTION: HARVARD PILGRIM HEALTH CARE

Budget	Year 1
Salaries and Wages	$140,347
Fringe Benefits	$41,823
Personnel Costs (Subtotal)	$182,170
Consultant Services	$5,000
Travel	$6,500
Subawards/Consortium/Contractual Costs	$500,845
TOTAL FEDERAL DC	$694,515
TOTAL FEDERAL F&A	$144,322
TOTAL COST	$838,837

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	66%
F&A Cost Base 1	$218,670
F&A Costs 1	$144,322

EXHIBIT B

This notice has expired. For NIH, in limited situations, applications may be accepted on a case-by-case basis for a short period after expiration to accommodate NIH late or continuous submission policies (https://grants.nih.gov/grants-process/submit/submission-policies). Contact the eRA Service Desk (https://www.era.nih.gov/need-help) for any submission issues. Check the NIH Guide (https://grants.nih.gov/funding/searchguide/) for active opportunities and notices.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

Office of Behavioral and Social Sciences Research (OBSSR (https://obssr.od.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS (https://www.niams.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (https://www.nichd.nih.gov/))

National Institute on Drug Abuse (NIDA (https://www.drugabuse.gov/))

National Institute of Nursing Research (NINR (https://www.ninr.nih.gov/))

National Institute on Minority Health and Health Disparities (NIMHD (https://www.nimhd.nih.gov/))

National Cancer Institute (NCI (https://www.cancer.gov/))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. OBSSR and the following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention (ODP (https://prevention.nih.gov/))

Office of Research on Women's Health (ORWH (https://orwh.od.nih.gov/))

EXPIRED

Funding Opportunity Title

Time-Sensitive Opportunities for Health Research (R61/R33 Clinical Trial Not Allowed)

Activity Code

R61 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r61&Search.x=0&Search.y=0&Search_Type=Activity)/R33 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r33&Search.x=0&Search.y=0&Search_Type=Activity)
Exploratory/Developmental Phased Award

Announcement Type

New

Related Notices

Case: 25-1611 Case 1:25-cv-10793-IT Document: 00117985095 Page: 3 Date Filed: 04/15/2025 Entry ID: 6756750

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=37757) associated with this funding opportunity

April 04, 2024 - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html)

February 29, 2024 - Notice of Change to Expiration Date for PAR-22-233 Time-Sensitive Opportunities for Health Research (R61/R33 Clinical Trial Not Allowed). See Notice NOT-OD-24-065 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-24-065.html)

December 01, 2023 - Notice of Change to Expiration Date for PAR-22-233. See Notice NOT-OD-24-016 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-016.html)

October 25, 2023 - Notice of Change to Expiration Date for PAR-22-233 Time-Sensitive Opportunities for Health Research (R61/R33 Clinical Trial Not Allowed) . See Notice NOT-OD-24-016 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-24-016.html)

NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available

NOT-OD-22-190 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022
September 28, 2022 - Notice of Information for Pre-Application Webinar for PAR-22-233. See Notice NOT-OD-22-222 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-22-222.html).

Funding Opportunity Announcement (FOA) Number

PAR-22-233

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.307, 93.279, 93.399, 93.313, 93.361, 93.273, 93.846, 93.865

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) establishes an accelerated review/award process to support research to understand health outcomes related to an unexpected and/or time-sensitive event (e.g., emergent environmental threat; pandemic; change in local, state, or national policy; natural disaster). Applications in response to this FOA must demonstrate that the research proposed is time-sensitive and must be initiated with minimum delay due to a limited window of opportunity to collect baseline data, answer key research questions, and/or prospectively evaluate a new policy or program. This FOA is intended to support opportunities in which empirical study could only be available through expedited review and funding, necessitating a substantially shorter process than the typical NIH grant review/award cycle. The time from submission to award is expected to occur within 4-5 months. However, administrative requirements and other unforeseen circumstances may delay issuance dates beyond that timeline.

Key Dates

Posted Date

September 01, 2022

Open Date (Earliest Submission Date)

November 01, 2022

Letter of Intent Due Date(s)

A0793

4 weeks prior to application due date

Application Due Date(s)

Applications will be accepted on a rolling basis, beginning November 1, 2022. Applications will be accepted through March 1, 2025.

All applications are due by 5:00 PM local time of applicant organization.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

Applications will be reviewed within 8 weeks.

Advisory Council Review

Applications will be reviewed on an expedited basis

Earliest Start Date

Within 4-6 months of application

Expiration Date

New Date March 2, 2025 (Original Date: November 02, 2023) per issuance of NOT-OD-24-065 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-24-065.html)

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.php?id=11164)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Table of Contents

Part 1. Overview Information
- Key Dates

Part 2. Full Text of Announcement
- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

BACKGROUND

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This Funding Opportunity Announcement (FOA) establishes an accelerated review/award process to support novel behavioral and social science research (BSSR) to understand health outcomes related to an unexpected and/or time-sensitive event. **Applications in response to this FOA must demonstrate that the research proposed is time-sensitive and must be initiated with minimum delay due to a limited window of opportunity to collect baseline data, answer key research questions, and/or prospectively evaluate a new policy or program that will likely impact health-related behavior or health outcomes in a given population.** In other words, the urgency of the public health problem being studied will not, on its own, be sufficient justification for time sensitivity.

RESEARCH SCOPE

This FOA is intended to support research and data collection for unanticipated real-world events (i.e., those that occur outside of a laboratory or other controlled setting for research purposes). These events inherently have limited windows of opportunity for planning and conducting rigorous research and data collection. It is critical that researchers maximize these learning opportunities to better inform health care and public health efforts, as well as policymakers.

Key Definitions for this FOA:

- An **event** is a unique and often unanticipated issue that arises in a particular community/population, due to emerging environmental threats, other public health threats, disaster events, or policy changes.
- **Policy** is broadly defined to include both formal public policies at local, state, and federal levels of government, and organizational level policies, such as those implemented by large organizations, worksites, or school districts.
- **Program** is defined as a set of activities such as implementation of system-level interventions, tools, or guidelines initiated by governmental or other organizational bodies, within public or private entities in local, state, or federal jurisdictions.
- **Infrastructure changes** are alterations to the built environment such as housing, roads and other aspects of transportation systems, retail environments, and building of parks or green spaces.

This FOA encourages partnerships and collaboration between researchers and the impacted community, which may include the following types of entities (as appropriate): community-based organizations, local and state governments, private or non-profit organizations, behavioral health or health care systems, individual health care providers, departments of health, community health clinics, juvenile or criminal justice settings, schools, child welfare systems, etc.

The distinguishing features of a responsive study are:

(1) The unpredictable and unanticipated nature of the research opportunity.

(2) The clear scientific value and feasibility of the study.

(3) A feasible plan for collection of baseline data and primary data collection (although use of existing data is allowed, a plan for collecting important and new data rapidly should be provided).

(4) A justification for why an expedited review and funding (substantially shorter than the typical NIH grant review/award cycle) are required in order for the scientific question(s) to be addressed and the research design to be implemented. Expected study methodologies may include, but are not limited to, interrupted time-series, difference-in-difference designs, regression discontinuity, or propensity scoring.

In situations where applications under this FOA focus on a particular locality (region, community, or other defined geographic area), note that findings should have the potential to be generalizable beyond the particular locality or population. Proposed studies should demonstrate the ability to inform the understanding of the impact of the event, policy, program or infrastructure change in the near-term. Applicants are encouraged to include secondary implementation related outcomes that could inform interpretation of outcomes for future researchers and decision-makers, such as unintended consequences or barriers and facilitators associated with implementation.

Applicants are also encouraged to review the NIH-led efforts that recommend research strategies for ensuring study rigor and reducing bias, such as including an appropriate comparison group where possible: NIH Pathways to Prevention (P2P) Workshop: Method for Evaluating Natural Experiments in Obesity (https://prevention.nih.gov/research-priorities/research-needs-and-gaps/pathways-prevention/methods-evaluating-natural-experiments-obesity). Furthermore, attention should be paid to ongoing developments in strengthening causal inference from evaluation of these natural experiments or observational study designs. Considerable progress has been made on this topic in public health, econometrics, and diverse aspects of policy research.

STRUCTURE

This FOA will utilize a bi-phasic, milestone-driven R61/R33 mechanism, consisting of a R61 phase with developmental activities and a R33 phase with expanded activities designed to achieve the full research aims. The R61 phase will be up to one year, and will support developmental, exploratory research, Institutional Review Board approval for human subjects protection, further development of study partnerships, and the collection of baseline data. The R33 phase will build on this initial work for up to four years to include further development, application, follow-up data collection, or implementation as appropriate and relevant to the proposed research questions.

The application should articulate clear aims and objectives for each phase of the proposed research, with specific discussion of how results from the R61 phase will inform the R33 phase. In addition, applications must delineate explicit milestones for the R61 and R33 phases. A milestone is defined as a scheduled event in the project timeline that indicates completion of a project stage or activity. **It is expected that**

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baseline data collection will be conducted within six months of award, which should be included in the applicant's submission of a project timeline and milestones. At the completion of the R61 phase, the Program Director (PD)/Principal Investigator (PI) will submit a report that includes the progress on each of the milestones and a clear description of how research during the R33 phase will be impacted by attainment of the R61 milestones. The IC program and other relevant staff will review the report and make recommendations on funding of the R33 grant based on two independent factors: 1) the preliminary research results and achievement of the milestones and 2) availability of funds and program priorities, irrespective of milestone achievements. Transition to the R33 phase is neither automatic nor guaranteed. Funding for the R33 phase is subject to availability of funds and program priorities, independent of milestone achievement. In addition, given the possibility for changes in policy or program implementation that are beyond the control of the grantee, grant awards may be terminated early if these changes limit the possibility to collect meaningful outcome data.

ADDITIONAL GUIDANCE

While applicants may propose to investigate time-sensitive opportunities outside the U.S., they must demonstrate within the application that all the proper logistics, human subjects concerns, and approvals, both domestic and international, can be addressed within the limited time frame outlined in this announcement. In addition, the applicant must demonstrate how information obtained from this study will have direct implications for US practice or policy.

Applicants are strongly encouraged to contact the relevant scientific contact(s) listed below to discuss whether their application would likely be responsive based on time-sensitivity four (4) weeks in advance of planned application.

Applications Not Responsive to this FOA

The following types of applications are not responsive to this FOA. Applications not responsive to this FOA will not be reviewed.

- Applications that do not explicitly justify the time sensitivity of the proposed work, the urgent need for data collection, and the need for an expedited review timeline. Include this explanation in the Significance section of the application.
- Applications that propose to use qualitative data exclusively (though mixed method approaches are encouraged).
- Applications that propose to conduct analyses of existing data exclusively (unless allowed in IC-specific interests).
- Applications aimed at addressing unanticipated needs or additional aims for an existing study (i.e., expansion of an existing study).
- Applications proposing to use animals (e.g., pets, laboratory animals, or wildlife) as surrogates for human health or exposure.
- Applications where the PD/PI of the evaluation study application is the Director and/or initiator of the policy, program, or infrastructure change that will be evaluated.
- Applications that independently propose initiation and/or delivery of new policies or programs.

All responsive applications to this FOA will be subject to an accelerated review and award process. It is intended that eligible applications selected for funding will be awarded within 4-5 months of the application due date. However, administrative requirements and other unforeseen circumstances may delay issuance dates beyond that timeline.

SPECIFIC AREAS OF RESEARCH INTEREST

National Cancer Institute (NCI)

NCI supports time-sensitive evaluation of programs, policies, and major events that concern aspects of cancer prevention and control including, but not limited to:

Evaluation of the effects of:

- Laws, regulations, or policies that may influence cancer risk factors including use of tobacco, alcohol, and other substances, sun safety and indoor tanning, diet, physical activity, and sleep.
- Changes to the built and natural environment involving factors such as housing, transportation infrastructure, food environment, parks and other green and blue spaces and the potential effect on cancer risk factors, exposure to environmental carcinogens, access to care, or other cancer-related health outcomes.
- Emerging programs and policies related to cancer screening, diagnosis, vaccination (e.g., HPV), treatment, and survivorship.
- New policies, programs, and practices in cancer care delivery related to standards of care, health insurance coverage, access to services, reimbursement, and other factors that influence delivery of cancer care services and its outcomes
- The impact and response to public health emergencies or disasters (natural or man-made) on acute stress, allostatic load or other aspects of accumulated stress, or cancer-related care, including preventative, diagnostic, treatment, and survivorship care.
- Natural and man-made disasters (e.g., chemical spills, fumes, weather events, and fires), and resulting environmental exposures on biomarkers, etiology, and healthcare delivery across the cancer control continuum.
- Natural and man-made disasters (e.g., chemical spills, fumes, weather events, and fires), and resulting environmental exposures on biomarkers, etiology, and healthcare delivery across the cancer control continuum.

Proposals evaluating policy and program efforts and responses to major events from diverse sectors, including government, educational, non-profit, and commercial sectors are of interest.

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

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NICHD has particular interest in research on time-sensitive events, policies, programs, or infrastructure changes on vulnerable populations falling within the NICHD scientific mission area, including infants, children, and adolescents and pregnant and post-partum people; individuals with physical and/or intellectual disabilities; and children who are unhoused or in foster care. The NICHD Strategic Plan (https://www.nichd.nih.gov/about/org/strategicplan) outlines high priority areas for the Institute.

Examples of research questions include but are not limited to the following:

- Understanding the short- and long-term impact of the time-sensitive event on child development outcomes, as well as family functioning.
- The impact of climate/environmental changes on dietary patterns, food choices, and eating behaviors.
- How changes in access to school lunch programs affect dietary patterns, food choices, and eating behaviors in children and their families.
- The impact of the event and the concomitant public health response on the management of complex medical conditions, critical illness, and severe, life-threatening injuries in children.
- The impact of the event on emergency medical services to children (EMSC) and the availability of these services during and after the event to affected children in low- to moderate- resourced communities.
- Studies identifying and developing data sources, tools and resources needed to strengthen tracking, reporting and communication among systems of care for traumatized, injured and affected children during and after the unexpected event.
- The impact of the event and the concomitant public health response on children and adults with physical and/or intellectual disabilities, and disparities in outcomes experienced by persons with disabilities compared to persons without disabilities.
- Studies that examine how unexpected disruptions in access to therapies and special education services affect developmental, behavioral and functional outcomes in children and adults with disabilities.

National Institute on Drug Abuse (NIDA)

This notice of funding opportunity (NOFO) will support pilot, feasibility or exploratory research in priority areas in substance use epidemiology, prevention, and health services, including: 1) responses to sudden and severe emerging drug issues (e.g. the ability to look into a large and sudden spike in opioid or synthetic cannabinoid use/overdoses in a particular community); 2) responses to emerging marijuana trends and topics related to the shifting policy landscape, related to imminent policy change; 3) responses to unexpected and time-sensitive prescription drug abuse research opportunities (e.g., new state or local efforts); 4) responses to unexpected and time-sensitive medical system issues (e.g. opportunities to understand addiction services in the evolving health care system); 5) responses to unexpected and time-sensitive criminal or juvenile justice opportunities (e.g. new system and/or structural level changes) that relate to drug abuse and access and provision of health care service; 6) partnerships between researchers and state or local organizations to support the evaluation of new local policies, programs, or practices in response to public health emergencies (e.g., the opioid crisis); 7) research examining how the COVID-19 pandemic has impacted drug markets and overdose risk; 8) research examining health outcomes associated with telehealth compared to in-person psychiatric care (e.g. risk of diversion/misuse, reduced treatment gap); 9) research examining the impact of the discontinuation of the Medicaid continuous enrollment provision that was enacted during the COVID-19 pandemic on populations with substance use disorders, and 10) research to understand outcomes related to states receiving and implementing Centers for Medicare and Medicaid Services (CMS) 1115 waivers that allow Medicaid to pay for health care services in carceral settings.

National Institute on Minority Health and Health Disparities (NIMHD)

The mission of NIMHD is to lead scientific research to improve minority health and reduce health disparities. NIMHD focuses on all aspects of health and health care for racial and ethnic minority populations in the U.S. and the full continuum of health disparity causes as well as the interrelation of these causes. NIMHD projects should include a focus on racial and ethnic minority populations (African Americans/Blacks, Latinos/Hispanics, American Indians and Alaska Natives, Asian Americans, Native Hawaiians and Pacific Islanders) and or less privileged socioeconomic groups, Projects may also examine intersectionality of race or ethnic minority identity and/or low socioeconomic status with rurality and/or sexual and gender minority identity and/or disability condition. Comparison groups/populations may also be included as appropriate for the research questions posed. NIMHD encourages research projects that use approaches encompassing multiple domains of influence (e.g., biological, behavioral, sociocultural, environmental, physical environment, health system) and multiple levels of influence (e.g., individual, interpersonal, family, peer group, community, societal) to understand and address health disparities (see the NIMHD Research Framework, https://www.nimhd.nih.gov/about/overview/research-framework.html, for more information). Studies based outside the U.S. or its territories will not be supported by NIMHD under this FOA. Time-sensitive research that NIMHD is interested in supporting includes:

- The effects of policy changes on health outcomes, and mechanisms of those health outcomes, in populations that experience health disparities, including: immigration policy, health care coverage, gun policy, police use-of-force policy, environmental regulations, prescribing practices, and vaccination requirements
- The immediate and longer-term impact of natural disasters on the health of populations that experience health disparities (particularly through the lens of understanding how climate change is impacting health disparities)
- Effects of changes to the built environment (e.g., greenspace, pedestrian walkways, bike paths) on health and health behaviors for populations that experience health disparities

National Institute of Nursing Research (NINR)

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NINR supports research to solve pressing health challenges and inform practice and policy - optimizing health and advancing health equity into the future. NINR discovers solutions to health challenges through the lenses of health equity, social determinants of health, population and community health, prevention and health promotion, and systems and models of care. Drawing on the strengths of nursing's holistic, contextualized perspective, core values, and broad reach, NINR funds multilevel and cross-sectoral research that examines the factors that impact health across the many settings in which nurses work, including homes, schools, workplaces, clinics, justice settings, and the community. Observational, intervention, and implementation research are of interest to NINR.

Research is encouraged in the following areas:

- Factors involved in a response to a time-sensitive event that affect health equity, including mechanisms involved.
- Effects of social determinants of health on the response to and health effects resulting from a time-sensitive event.
- Prevention and early detection of health effects of a time-sensitive event, including plans for health promotion during and following the event.
- Examining clinical, organizational and/or policy changes to address health related needs during and following a time-sensitive event.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

NIAAA will support time-sensitive research in public health priority areas in alcohol and related substance use epidemiology, prevention, and health services, including but not necessarily limited to:

- time-sensitive research opportunities to study the effects of changes in alcohol-related policies, including effects on combined use of alcohol and other substances and evaluation of the implementation or effectiveness of policies, programs, or practices affecting alcohol-related behaviors and outcomes;
- time-sensitive research opportunities to study changes in factors affecting access, delivery, or financing of health care services for alcohol use disorder and alcohol-related conditions;
- time-sensitive research opportunities to study alcohol-related effects associated with sudden and severe events, such as natural disasters, acts of war, or epidemics;
- time-sensitive research opportunities to study the effects on diversity, health equity, inclusion, or access of unanticipated events affecting alcohol-related behaviors and outcomes; and
- time-sensitive research opportunities to inform state or local organizations of the alcohol-related consequences of new or changing policies, programs, or practices.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

NIAMS is interested in applications focused on evaluating time-sensitive natural experiments that concern populations with or at risk for development of NIAMS core-mission diseases (arthritic and other rheumatic, musculoskeletal, and skin disorders. Examples include, but are not limited to, time-sensitive natural experiments of changes to the neighborhood food and physical activity environments on the health of populations experiencing or at risk for NIAMS core-mission diseases. Studies among underserved, vulnerable, diverse and health disparities populations are encouraged.

Office of Disease Prevention (ODP)

The ODP is the lead office at the NIH responsible for assessing, facilitating, and stimulating research in disease prevention. In partnership with the 27 NIH Institutes and Centers, the ODP strives to increase the scope, quality, dissemination, and impact of NIH-supported prevention research. The ODP co-funds research that has strong implications for disease and injury prevention and health equity and that includes innovative and appropriate research design, measurement, and analysis methods. The ODP has a specific interest in projects that develop and/or test preventive interventions. Of particular interest is prevention research addressing leading causes and risk factors for premature morbidity and mortality, dissemination and implementation, and health disparities. The ODP does not award grants; therefore, applications must be relevant to the objectives of at least one of the participating NIH Institutes and Centers (IC) listed in this announcement. Please contact the relevant IC Scientific/Research Contact(s) listed for questions regarding IC research priorities and funding. ODP only accepts co-funding requests from NIH Institutes and Centers (ICs). For additional information about ODP, please refer to the ODP Strategic Plan for Fiscal Years 2019 2023 (https://prevention.nih.gov/about-odp/strategic-plan-2019-2023).

Office of Research on Women's Health (ORWH)

ORWH works with the 27 NIH Institutes and Centers to advance rigorous research of relevance to women and individuals assigned female at birth. For this funding opportunity, ORWH is particularly interested in intersectional research into the health impacts of time-sensitive events, policies, programs, or infrastructure changes on women, including:

- Impacts of policy changes on the health of women and people who can become pregnant (e.g., state abortion regulations, extensions to postpartum insurance coverage)
- Impacts of policy changes that influence access to women's preventative health services (e.g., contraception, HPV vaccination, pre-exposure prophylaxis (PrEP))
- Gender-based violence following time-sensitive events (e.g., natural disasters; pandemics)

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

Funds Available and Anticipated Number of Awards

PA/PAR:

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited but need to reflect the actual needs of the proposed project.

Award Project Period

The scope of the proposed project should determine the requested project award period.

The maximum period of the combined R61 and R33 phases is 5 years, with up to 1 year for the R61 phase and up to 4 years for the R33 phase.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)

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- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Government

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- System for Award Management (SAM) (https://grants.nih.gov/grants/guide/url_redirect.php?id=82390) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
    - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

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- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11126).

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per 2.3.7.4 Submission of Resubmission Application (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.7_policies_affecting_applications.htm#Submissi). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see 2.3.9.4 Similar, Essentially Identical, or Identical Applications (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Similar,)).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

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The letter of intent should be sent to:

Rosalind King, PhD
Office of Behavioral and Social Sciences Research (OBSSR)
Phone: 301-451-3832
Email: kingros@nih.gov (mailto:kingros@nih.gov)

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.php?id=11133) must be followed.

Instructions for Application Submission

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing (DMS) Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy: Applications should justify the time sensitivity of the proposed work, the urgent need for data collection, and the need for an expedited review timeline in the Significance section of the application.

The Research Strategy should include a description of both the R61 and R33 phases, each with clear aims and objectives. Include a specific section labeled "Milestones". Milestones should be clearly described, feasible, well developed, quantifiable, and scientifically justified to transition to the R33 phase. A discussion of the milestones relative to the progress of the R61 phase and the implications of successful completion of the milestones for the R33 phase should be included. **It is expected that baseline data collection will be conducted within six months of award, which should be included in the applicant's submission of a project timeline and milestones.**

If applicable and proposing to investigate time-sensitive opportunities outside the U.S., the application must include information demonstrating that all the proper logistics, human subjects concerns, and approvals, both domestic and international, can be addressed

within the limited time frame outlined in this announcement. In addition, the applicant must demonstrate how information obtained from this study will have direct implications for US practice or policy.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered Yes to the question Are Human Subjects Involved? on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission. This FOA accepts applications on a rolling basis. Applications are reviewed on an expedited schedule and assigned to an Advisory Council round based on their actual submission date. Because the Scientific Merit Review assignment deadline listed in Part 1. Key Dates is not an application due date, the NIH Policy on Late Application Submission does not apply to the Scientific Merit Review or Advisory Council round assigned.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm).

6. Funding Restrictions

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All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential fieldof the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete , non-compliant or non-responsive will not be reviewed.

Requests of $500,000 or more for direct costs in any year

Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.php?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Milestones and timeline: Is there a unifying research question that transcends both R61 and R33 phases? Does the application provide well described, feasible and quantifiable milestones for the R61 phase and related scientific goals and objectives for the R33 phase? Are those milestones conducive to accomplishing the study aims? Are the goals of the R33 phase based, in part, on findings collected during the R61 phase? Does the timeline demonstrate baseline data collection within six months of award?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

If applicable and proposing to investigate time-sensitive opportunities outside the U.S., is there appropriate justification of how the information obtained from the study will have direct implications for US practice and/or policy? Is there adequate information provided demonstrating that all the proper logistics, human subjects concerns, and approvals, both domestic and international, can be addressed within the limited time frame outlined in this announcement.

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and

3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url_redirect.php?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.php?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (//grants.nih.gov/grants/guide/url_redirect.php?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Time Sensitivity

Reviewers will assess whether or not (i.e., yes/no) applications demonstrate the time sensitivity of the research opportunity; in other words, will an important opportunity for scientific inquiry and data collection be lost if the work is not initiated in an expedited way (i.e., with minimum delay). It should be clear that the knowledge gained from the proposed study is time-sensitive such that an expedited review and funding are required in order for the scientific question(s) to be answered. Reviewers are also asked to determine whether or not the event described in the application offers an uncommon and scientifically compelling opportunity that might only be available through this mechanism. Of particular relevance is that an expedited award would facilitate baseline data collection at a critical point in the timeline of the event in question.

Applications from Foreign Organizations

Not Applicable.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.php?id=11151); (2) Sharing Model Organisms (https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview); and (3) Genomic Data Sharing Plan (GDS) (https://sharing.nih.gov/genomic-data-sharing-policy).

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by Center for Scientific Review (CSR) in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159), including of note, but not limited to:

- Federalwide Research Terms and Conditions (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)
- Acknowledgment of Federal Funding (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identify, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html)

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov/).
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including reasonable accommodations and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).
- For guidance on administering programs in compliance with applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other

information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement (/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

3. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm)

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH FOAs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.8_federal_funding_accountability_and_transparency_act__ffata_.htm) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726

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Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

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Bramaramba Kowtha MS, RDN, LDN
Office of Disease Prevention (ODP)
Telephone: 301-435-8052
Email: bramaramba.kowtha@nih.gov

Peer Review Contact(s)

Center for Scientific Review (CSR)
Email: FOAReviewContact@csr.nih.gov (mailto:FOAReviewContact@csr.nih.gov)

Financial/Grants Management Contact(s)

The Office of Behavioral and Social Sciences Research (OBSSR (https://obssr.od.nih.gov/)) cannot accept assignments of applications or manage funded research projects. Please contact the IC-based grants management professionals below for related inquiries .

Judy Fox
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Telephone: 301-443-4707
Email: jfox@mail.nih.gov (mailto:jfox@mail.nih.gov)

Ron Wertz
National Institute of Nursing Research (NINR)
Telephone: 301-594-2807
Email: wertzr@mail.nih.gov (mailto:wertzr@mail.nih.gov)

Sahar Rais-Danai
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Phone: 301-594-5032
E-mail: sahar.rais-danai@nih.gov (mailto:sahar.rais-danai@nih.gov)

Priscilla Grant
National Institute on Minority Health and Health Disparities (NIMHD)
Phone: 301-594-8412
E-mail: pg38h@nih.gov (mailto:pg38h@nih.gov)

Margaret Young
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
Telephone: 301-642-4552
Email: margaret.young@nih.gov (mailto:margaret.young@nih.gov)

Pamela G Fleming
National Institute on Drug Abuse (NIDA)
Phone: 301-480-1159
E-mail: pfleming@mail.nih.gov (mailto:pfleming@mail.nih.gov)

Crystal Wolfrey
National Cancer Institute (NCI)
Phone: 240-276-6277
Email: crystal.wolfrey@nih.gov

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.php?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?09-02-22)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

NIH National Institutes of Health (/grants/oer.htm)
Office of Extramural Research

(https://www.hhs.gov/) Department of Health and Human Services (HHS)

USA.gov (https://www.usa.gov/)

NIH... Turning Discovery Into Health®

EXHIBIT C

National Institutes of Health
Office of Extramural Research

March 12, 2025

Cary Williams
Harvard Pilgrim Health Care
Email: research_admin@hphci.harvard.edu

Dear Cary Williams:

Funding for Project Number 1R61HD117134-01 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on August 22, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research program.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

1R61HD117134-01 is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, ***on behalf*** of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT D

Case: 25-1814 Case: 25-1814 Document: 00118135099 Document: 00118135099 Page: 3719 Page: 3719 Date Filed: 12/15/2025 Date Filed: 12/15/2025 Page 50 of 97 Page 50 of 97 Entry ID: 6736790 Entry ID: 6736790

Recipient Information

1. Recipient Name
uASVASK PlOGSIM uhAORu UASh l6U
1 3 hOO6hYY 3 AD
UA6RT6WMA 02021

2. Congressional District of Recipient
0,

3. Payment System Identifier (ID)
1042452#00A1

4. Employer Identification Number (EIN)
042452#00

5. Data Universal Numbering System (DUNS)
0717210, ,

7. Recipient6s Uni' ue Entity Identifier
6ZVVQ, G6VX#5

q. Project Director or Principal Investigator
Brittany MicHeNe UHarNonWKYU
Assistant Professor
bcHarNon@maiNHarvard.edl
#17-4##-92#2

8. Authorized Official
Uary 3 iNNams

Federal Agency Information

9. Awarding Agency Contact Information
Dvonne U. RaNNy
Grants Management TfficiaN
hE6lUh Ch66hKD YuSlVhS 6ARlT6AO
l6YRlRERh TL UulOK uhAORu F uEMA6
KhVhOTPMh6R
taNNyy@maiNniHgov
801-49#-7482

10. Program Official Contact Information
Sonna Popkin

hE6lUh Ch66hKD YuSlVhS 6ARlT6AO
l6YRlRERh TL UulOK uhAORu F uEMA6
KhVhOTPMh6R
ronna.popkin@niHgov
801-, 27-5121

Federal Award Information

11. Award Number
1S#1uK117184-01

12. Uni' ue Federal Award Identification Number (FAIN)
S#1uK117184

13. Statutory Authority
42 EYU 241 42 ULS PASR 52

14. Federal Award Project Title
Yl pportive and restrictive factors and mentaN-HeaNH in OGBR adoNescent and yol ng adl NlpopI Nations

15. Assistance Listing Number
98., #5

17. Assistance Listing Program Title
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1q. Award Action Type
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18. Is the Award R&D?
Des

Summary Federal Award Financial Information

19. Budget Period Start Date 0, /2#/2024 **– End Date** 08/12/2025	
20. Total Amount of Federal Funds Obligated by this Action	j 0
20 a. Kirect Uost AmoI nt	j 0
20 b. Indirect Uost AmoI nt	j 0
21. AI tHori" ed Uarryover	
22. Tffset	
23. RotaNAmoI nt of LederaNLI nds TbNgated tHis bI dget period	j , 8, W87
24. Total Approved Cost Sharing or Matching, where applicable	j 0
25. Total Federal and Non-Federal Approved this Budget Period	j , 8, W87
27. Project Period Start Date 0, /2#/2024 **– End Date** 08/12/2025	
2q. RotaNAmoI nt of tHe LederaNAward incNding Approved Uost YHaring or MatcHing tHis Proqect Period	j , 8, W87

28. Authorized Treatment of Program Income
AdditionaNUosts

29. Grants Management Officer - Signature
Margaret A. DoI ng

30. Remarks

Acceptance of tHis awardWincNding tHe _Rerms and UonditionsWis acknowNedged by tHe recipient wHen fI nds are drawn down or otHerwise re(I ested from tHe grant payment system.

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Phase 1 Exploratory/Developmental Grant
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SECTION I – AWARD DATA – 1R71HD11q134-01 RE: ISED

Principal Investigator(s)/
Brittany MicHeNe UHarNonW KYU

Award e-mailed to/ researcH‘admin@HpHci.Harvard.edl

Kear Al tHori" ed TfficiaN

RHe 6 ationaNnstitl tes of u eaNH Hereby revises tHis award $see ”Award UaNl Nation) in Yection l and ”Rerms and Uonditions) in Yection lllz to u ASVASK PlOGSlM u hAORu UASh in sl pport of tHe above referenced proqect. RHis award is pl rsl ant to tHe al tHority of 42 EYU 241 42 ULS PASR 52 and is sl bqect to tHe re(l irements of tHis statl te and regl Nation and of otHer referencedWncorporated or attacHed terms and conditions.

Acceptance of tHis awardWncN ding tHe _Rerms and UonditionsW is acknowNedged by tHe recipient wHen fl nds are drawn down or otHerwise re(l ested from tHe grant payment system.

hacHpl bNcationWpress reNeaseWor otHer docl ment abol t researcH sl pported by an 6 lu award ml st incN de an acknowNedgment of 6 lu award sl pport and a discNaimer sl cHas ”SesearcH reported in tHis pl bNcation was sl pported by tHe hl nice Cennedy YHriver 6 ationaNnstitl te Tf UHiNd u eaNH F u l man KeveNopment of tHe 6 ationaNnstitl tes of u eaNH l nder Award 6 l mber S#1u K117184. RHe content is soNeNy tHe responsibiNty of tHe al tHors and does not necessariNy represent tHe officiaNviews of tHe 6 ationaNnstitl tes of u eaNH.) Prior to issl ing a press reNease concerning tHe ol tcome of tHis researcH WpNease notify tHe 6 lu awarding lU in advance to aNow for coordination.

Award recipients ml st promote obqectivity in researcH by estabNsHing standards tHat provide a reasonabNe expectation tHat tHe designWcondl ct and reporting of researcH fl nded l nder 6 lu awards wiNNbe free from bias resl Nting from an lnvestigator’s LinanciaNUonfNct of lnterest $LUTlzWn accordance witH tHe 2011 revised regl Nation at 42 ULS Part 50 Yl bpart L. RHe lnstitl tion sHaNNsl bmit aNNLUTl reports to tHe 6 lu tHrol gH tHe eSA Uommons LUTl Modl Ne. RHe regl Nation does not apNy to PHase l YmaNNBl siness lnnovative SesearcH $YBlSz and YmaNNBl siness RecHnoNogy Rransfer $YRRSz awards. Uonsl Nt tHe 6 lu website Http://grants.niH.gov/grants/poNcy/coi/ for a Nnk to tHe regl Nation and additionaNlmportant information.

lf yol Have any (l estions abol t tHis awardWpNease direct (l estions to tHe LederaNAgency contacts.

YincereNy yol rsW

Margaret A. Dol ng
Grants Management Tfficer
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AdditionaNnformation foNows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	j 140W847
Fringe Benefits	j 41W28
Personnel Costs (Subtotal)	j 1, 2W70
Consultant Services	j 5W000
Travel	j #W500
SubawardsYConsortiumYContractual Costs	j 500W45
Federal Direct Costs	j #94W515
Federal F&A Costs	j 144W822
Approved Budget	j , 8, W87
Total Amount of Federal Funds Authorized (Federal Share)	j , 8, W87
TOTAL FEDERAL AWARD AMOUNT	j , 8, W87
AMOUNT OF THIS ACTION (FEDERAL SHARE)	j 0

SUMMARV TOTALS FOR ALL VEARS $for tHis KocI ment 6 I mberz		
VR	**THIS AWARD**	**CUMULATI: E TOTALS**
1	j , 8, W87	j , 8, W87

Fiscal Information/

Payment System Identifier/	1042452#00A1
Document Number/	Su K117184A
PMS Account Type/	P $YI baccoI ntz
Fiscal Vear/	2024

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NIH Administrative Data/
PCC: PKB -SP / **OC**: 41021 / **Released**: 08/14/2025
Award Processed/ 08/15/2025 12:09:47 AM

SECTION II – PAVMENTYHOTLINE INFORMATION – 1R71HD11q134-01 RE: ISED

Lor payment and u uY Tffice of lnspector GeneraNu otNhe informationWsee tHe 6 lu u ome Page at Http://grants.niHgov/grants/poNcy/awardconditions.Htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R71HD11q134-01 RE: ISED

RHis award is based on tHe appNcation sI bmitted toWand as approved byW6 lu on tHe above-titNd proqect and is sI bqect to tHe terms and conditions incorporated eitHer directNy or by reference in tHe foNwing:

a. RHe grant program NegisNation and program regI Nation cited in tHis 6 otice of Award.
b. Uonditions on activities and expenditI re of fI nds in otHer statI tory re(I irementsWsI cH as tHose incNded in appropriations acts.
c. 45 ULS Part 75.
d. 6 ationaNPoNcy Se(I irements and aNotHer re(I irements described in tHe 6 lu Grants PoNcy YtatementWincNding addenda in effect as of tHe beginning date of tHe bI dget period.
e. LederaNAward Performance GoaNs: As re(I ired by tHe periodic report in tHe SPPS or in tHe finaN progress report wHen appNcabN.
f. RHis award noticeW6 UOEKI6 G Ru h RhSMY A6 K UT6 KIRIT6 Y UIRhK BhOT3 .

$Yee 6 lu u ome Page at Http://grants.niHgov/grants/poNcy/awardconditions.Htm for certain references cited above.z

Research and Development (R&D)/ AN awards issI ed by tHe 6 ationaNnstitI tes of ueaNH $6 lu z meet tHe definition of "SesearcHand KeveNopment) at 45 ULS PartS 75.2. As sI cHWaI ditees sHoI Nd identify 6 lu awards as part of tHe SFK cNster on tHe YcHedI Ne of hxpenditI res of LederaNAwards $YhLAz RHe aI ditor sHoI Nd test 6 lu awards for compNance as instrI cted in Part VWUNsters of Programs. 6 lu recogni" es tHat some awards may Have anotHer cNassification for pI rposes of indirect costs. RHe aI ditor is not re(I ired to report tHe disconnect $i.e.WHe award is cNassified as SFK for LederaNAI dit Se(I irement pI rposes bI t non-

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In accordance witH P.O. 110-1#1Wcompliance witHtHe 6lu PI bNc Access PoNcy is now mandatory. Lor more informationWsee 6TR-TK-0, -088 and tHe PI bNc Access website: Http://pI bNcaccess.niHgov/.

RHis award represents tHe finaNyear of tHe competitive segment for tHis grant. Yee tHe 6lu Grants PoNcy Ytatement Yection , .# UNoseoI t for compNete cNoseoI t re(I irements at: Http://grants.niHgov/grants/poNcy/poNcy.Htm&gps.

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EnNess an appNcation for competitive renewaNs sI bmittedWa LinaNSesearcH Performance Progress Seport $LinaNSPPSzmI st aNso be sI bmitted witHin 120 days of tHe period of performance end date. If a competitive renewaNappNcation is sI bmitted prior to tHat dateWtHen an Interim SPPS mI st be sI bmitted by tHat date as weNNInstrI ctions for preparing an Interim or LinaNSPPS are at: Https://grants.niHgov/grants/rppr/rppr“instrI ction“gI ide.pdf. Any otHer specific re(I irements set fortHin tHe terms and conditions of tHe award mI st aNso be addressed in tHe Interim or LinaNSPPS. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

6lu re(I ires eNectronic sI bmission of tHe finaNnvention statement tHroI gHtHe UNoseoI t featI re in tHe Uommons.

6TRh: If tHis is tHe finaNyear of a competitive segment dI e to tHe transfer of tHe grant to anotHer institI tionW tHen a LinaNSPPS is not re(I ired. uoweverWa finaNexpenditI re LLS is re(I ired and mI st be sI bmitted eNectronicaNNy as noted above. If not aNeady sI bmittedWtHe LinaNnvention Ytatement is re(I ired and sHoI Nd be sent directNy to tHe assigned Grants Management YpeciaNst.

RHis award is fI nded by tHe foNowing Nist of institI tes. Any papers pI bNisHed I nder tHe aI spices of tHis award mI st cite tHe fI nding sI pport of aNInstitI tes.

TffiTf RHe KirectorWoationaNnstitI tes Tf u eaNH $TKz

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- Secipients of LLA mI st ensI re tHat tHeir programs are accessibNe to persons witHNimited hngNisH proficiency. Lor gI idance on meeting tHe NegaNobNigation to take reasonabNe steps to ensI re meaningfI Naccess to programs or activities by Nimited hngNisH proficient individI aNsW see HttpsWwww.HHs.govciviNrigHtsfor-individI aNsspecaNtopicsNimited-engNisH-proficiencyfact-sHeet-gI idanceindex.HtmNand HttpsWwww.Nep.gov.
- Lor information on an institI tion's specific NegaNobNigations for serving (I aNfied individI aNs witH disabiNitiesWincNuding providing program accessWeasonabNe modificationsWand to provide effective commI nicationWsee HttpWwww.HHs.govocrciviNigHtsI nderstandingdisabiNityindex.HtmN
- u u Y fI nded HeaNHand edI cation programs mI st be administered in an environment free of sexI aN Harassment; see HttpsWwww.HHs.govciviNrigHtsfor-individI aNssex-discriminationindex.HtmN Lor information aboI t 6 Iu 's commitment to sI pporting a safe and respectfI Nwork environmentW wHo to contact witH(I estions or concernsWand wHat 6 Iu 's expectations are for institI tions and tHe individI aNs sI pported on 6 Iu -fI nded awardsWpNease see HttpsWgrants.niHgovgrantspoNicyHarassment.Htm.
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In accordance witHtHe regI Natory re(I irements provided at 45 ULS 75.118 and Appendix XII to 45 ULS Part 75Wecipients tHat Have cI rrentNy active LederaNgrantsWcooperative agreementsWand procI rement contracts witHcI mI Native totaNvaNe greater tHan j 10W000W000 mI st report and maintain information in tHe Yystem for Award Management $YAMz aboI t civiNcriminaNand administrative proceedings in connection witHtHe award or performance of a LederaNaward tHat reacHed finaNdisposition witHin tHe most recent five-year period. RHe recipient mI st aNso make semiannI aNdiscNosI res regarding sI cHproceedings. Proceedings information wiNNbe made pI bNicNy avaiNabNe in tHe designated integrity and performance system $cI rrentNy tHe LederaNAwardee Performance and Integrity lnformation Yystem $LAPIlYzz LI NNreporting re(I irements and procedI res are foI nd in Appendix XII to 45 ULS Part 75. RHis term does not appNy to 6 Iu feNNowsHips.

Treatment of Program Income/
AdditionaNUosts

SECTION I: – HD SPECIFIC AWARD CONDITIONS – 1R71HD11q134-01 RE: ISED

UNnicaNRriaNndicator: 6 o
RHis award does not sI pport any 6 Iu -defined UNnicaNRriaNs. Yee tHe 6 Iu Grants PoNicy Ytatement Yection 1.2 for 6 Iu definition of UNnicaNRriaN.

REVISION: This revised award terminates the budget, and the project end dates to 03/12/2025.

It is the policy of NIH not to prioritize Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research

programs. Therefore, this project is terminated. HARVARD PILGRIM HEALTH CARE, INC., may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered.

Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. Â§ 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Kata Management and YHaring Poli cy: Appli cable

RHis proqect is expected to generate scientific data. RHerefore WHe LinaN6 lu Poli cy for Kata Management and YHaring appli es. RHe approved Kata Management and YHaring $KMYz Pli an is Hereby incorporated as a term and condition of award Wand tHe recipient sHall manage and disseminate scientific data in accordance witH tHe approved pli an. Any significant cHanges to tHe KMY Pli an $e.g. Wnew scientific direction Wa different data repository Wor a timeli ne revision zre(I ire 6 lu prior approval Lail Ni re to comply witH tHe approved KMY pli an may resI lt in sI spension and/or termination of tHis award WitHHolding of sI pport Wal dit disallowances W and/or otHer appropriate action. Yee 6 lu Grants Poli cy Ytatement Yection , .2.8 for more information on data management and sHaring expectations.

SPREADSHEET SUMMARV
AWARD NUMBER/ 1S#1u K117184-01 ShVlYhK

INSTITUTION/ u ASVASK PIOGSIM u hAORu UASh

BI dget	Dear 1
Yalaries and 3 ages	j 140W847
Lringe Benefits	j 41W28
PersonneLUosts $YI btotal	j 1, 2W70
UonsI ltant Yervices	j 5W000
RraveL	j #W500
YI bawards/Uonsortil m/UontractI aLUosts	j 500W45
RTRAOLhKhSAOKU	j #94W515
RTRAOLhKhSAOLFA	j 144W822
RTRAOUTYR	j , 8, W87

LaciLities and Administrative Uosts	Dear 1
LFA Uost Sate 1	##%
LFA Uost Base 1	j 21, W70
LFA Uosts 1	j 144W822

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/15/2025 12:09 AM

EXHIBIT E

Recipient Information

1. Recipient Name
CHILDREN'S HOSPITAL CORPORATION, THE
300 LONGWOOD AVE

BOSTON, MA 02115

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1042774441A1

4. Employer Identification Number (EIN)
042774441

5. Data Universal Numbering System (DUNS)
076593722

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
Brittany Michelle Charlton, DSC
Assistant Professor
bcharlton@mail.harvard.edu
857-218-5463

8. Authorized Official
Jamie Chan

Federal Agency Information

9. Awarding Agency Contact Information
CARLA GRIFFITH
Grants Management Specialist
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
griffithcp@mail.nih.gov
301-594-8944

10. Program Official Contact Information
DOROTHY M CASTILLE
Health Scientist Administrator
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
dorothy.castille@nih.gov
301-594-9411

Federal Award Information

11. Award Number
1R01MD015256-01A1

12. Unique Federal Award Identification Number (FAIN)
R01MD015256

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Sexual orientation-related disparities in obstetrical and perinatal health

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 05/16/2021 – **End Date** 02/28/2022	
20. Total Amount of Federal Funds Obligated by this Action	$929,389
20 a. Direct Cost Amount	$580,577
20 b. Indirect Cost Amount	$348,812
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$929,389
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$929,389
26. Project Period Start Date 05/16/2021 – **End Date** 02/28/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$929,389

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Priscilla Grant

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 1R01MD015256-01A1

Principal Investigator(s):
Brittany Michelle Charlton, DSC

Award e-mailed to: osp@childrens.harvard.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $929,389 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to BOSTON CHILDREN'S HOSPITAL in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD015256. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Priscilla Grant
Grants Management Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Version: 203 - 1/27/2021 10:14 PM | Generated on: 5/16/2021 8:13 AM

Salaries and Wages	$207,078
Fringe Benefits	$82,310
Personnel Costs (Subtotal)	$349,418
Consultant Services	$19,200
Materials & Supplies	$1,000
Travel	$7,500
Other	$885
Subawards/Consortium/Contractual Costs	$202,574
Federal Direct Costs	$580,577
Federal F&A Costs	$348,812
Approved Budget	$929,389
Total Amount of Federal Funds Authorized (Federal Share)	$929,389
TOTAL FEDERAL AWARD AMOUNT	$929,389
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$929,389

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$929,389	$929,389
2	$859,031	$859,031
3	$849,882	$849,882
4	$849,117	$849,117
5	$846,211	$846,211

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1042774441A1
Document Number: RMD015256A
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021	2022	2023	2024	2025
MD	8472687	$929,389	$859,031	$849,882	$849,117	$846,211

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CPS01DC / **OC**: 41021 / **Released**: Grant, Priscilla 05/09/2021
Award Processed: 05/16/2021 08:13:51 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01MD015256-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01MD015256-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

Terms and Conditions of Award, Publication Requirements, and all Terms and Conditions Cited in NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.

e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MD015256. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REQUIREMENT: This award is subject to the conditions set forth in PA-20-185, NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 05/05/20, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

INFORMATION The committed levels for future years reflect the removal of inflationary escalation.

INFORMATION In order to redistribute awards more evenly throughout the year, budget periods are being adjusted. This award is issued with a 9.5 month budget period and with 12 months of support. Continuation awards will cycle each year on March 1st.

INFORMATION: Although the budget period start date for this award is May 16th, this award includes funds for 12 months of support. Future year budget periods will cycle on March 1st. Allowable preaward costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement, and with institutional requirements for prior approval. The NIH GPS can be found on the internet at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

REQUIREMENT: Use of humans and animals in any new activities must be requested prior to the start of the activity and must be approved in writing in advance by the NIMHD. See NOT-MD-08-002, "Guidance and Clarification on NCMHD Policy on Prior Approval for Subprojects and Pilot Projects Involving Human Subjects or Vertebrate Animals," NIH Guide to Grants and Contracts, April 29, 2008, which is hereby incorporated by reference as special terms and conditions of this award. See also NOT-OD-15-129, "Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice," and NIH-OD-15-128, "Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice."

Copies of these Notices may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

INFORMATION: This award reflects the NIMHD's acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with NIH policy, "Required Education in the Protection of Human Research Participants," as announced in the June 5, 2000 NIH Guide (revised August 25, 2000) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html).

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

INFORMATION: See "Federalwide Assurance Requirements" and "Certification of IRB Approval" under the Human Subjects Protections section in the NIH Grants Policy Statement (NIHGPS), for specific requirements and recipient responsibilities related to the protection of human subjects, which are applicable to and are a term and condition of this award. The NIHGPS can found on the internet at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

INFORMATION: Funds awarded for direct cost compensation for Graduate Research Assistants are limited in accordance with the NIH policy.

INFORMATION None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. See the new Salary Limitations on Grants: https://grants.nih.gov/grants/policy/salcap_summary.htm

INFORMATION: Unobligated balances may be used by the NIMHD to reduce or offset funding for a subsequent budget period.

INFORMATION: Regarding changes in scope, attention is called to the NIH Grants Policy Statement. The Change in Scope section is found in Section 8.1.2 at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf. The recipient must obtain prior approval from the NIMHD for a change in the direction, aims, objectives, purposes, or type of research or training, or other areas that constitute a significant change in the approved project. Specific examples are provided.

INFORMATION: Regarding allowability of selected items of cost, attention is called to the NIH Grants Policy Statement. The Selected Items of Cost section is found in Section 7.9.1 at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

INFORMATION: Honoraria are unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable. See Section 7.9.1 at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

INFORMATION This award includes funds awarded for consortium activity. Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH GPS is available at: http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf. See "Consortium Agreements" in Section 15 for specific responsibilities and requirements for recipients and consortium participants, which are applicable to and are a term and condition of this award.

RESTRICTION: Stipends and payments made for educational assistance (e.g., scholarships, fellowships, and student aid costs) may not be paid from NIH research grant funds even when they would appear to benefit the research project (NIH GPS Section 7.9.1). Compensation must be in accordance with organizational policies consistently applied to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation for services rendered are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. (A stipend is a payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.) See the NIH Grants Policy Statement for allowable forms of student compensation, available at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01MD015256-01A1

INSTITUTION: BOSTON CHILDREN'S HOSPITAL

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$267,108	$262,190	$258,026	$251,047	$252,126
Fringe Benefits	$82,310	$79,969	$72,973	$73,520	$70,799
Personnel Costs (Subtotal)	$349,418	$342,159	$330,999	$324,567	$322,925
Consultant Services	$19,200	$19,200	$19,200	$19,200	$19,200
Materials & Supplies	$1,000	$1,000	$1,000	$1,000	$1,000
Travel	$7,500	$7,500	$7,500	$9,500	$9,500
Other	$885	$885	$885	$885	$885
Subawards/Consortium/Contractual Costs	$202,574	$202,814	$209,878	$209,878	$209,878
Publication Costs			$2,000	$6,000	$6,000
TOTAL FEDERAL DC	$580,577	$573,558	$571,462	$571,030	$569,388
TOTAL FEDERAL F&A	$348,812	$285,473	$278,420	$278,087	$276,823
TOTAL COST	$929,389	$859,031	$849,882	$849,117	$846,211

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	77%	77%	77%	77%	77%
F&A Cost Base 1	$453,003	$370,744	$361,584	$361,152	$359,510
F&A Costs 1	$348,812	$285,473	$278,420	$278,087	$276,823

EXHIBIT F

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
Notice of Award
FAIN# R01MD015256
Federal Award Date
02/18/2025
Recipient Information
1. Recipient Name
HARVARD PILGRIM HEALTH CARE INC
1 WELLNESS WAY
CANTON, MA 02021

2. Congressional District of Recipient
08

3. Payment System Identifier (ID)
1042452600A1

4. Employer Identification Number (EIN)
042452600

5. Data Universal Numbering System (DUNS)
071721088

6. Recipient's Unique Entity Identifier
NZVVQ8GNVX65

7. Project Director or Principal Investigator
Brittany Michelle Charlton, DSC
Assistant Professor
bcharlton@mail.harvard.edu
617-466-9262

8. Authorized Official
Charlotte Johnson
research_admin@harvardpilgrim.org

Federal Agency Information
9. Awarding Agency Contact Information
MICHELLE MAE Phillips
Grants Management Specialist
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
michelle.phillips@nih.gov
(301) 402-1366
10. Program Official Contact Information
Priscah Mujuru
Program Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
priscah.mujuru@nih.gov
301-594-9765

Federal Award Information

11. Award Number
5R01MD015256-05

12. Unique Federal Award Identification Number (FAIN)
R01MD015256

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Sexual orientation-related disparities in obstetrical and perinatal health

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information
19. Budget Period Start Date 03/01/2024 - End Date 04/30/2025
20. Total Amount of Federal Funds Obligated by this Action
$0
20 a. Direct Cost Amount
$0
20 b. Indirect Cost Amount
$0
21. Authorized Carryover

22. Offset

23. Total Amount of Federal Funds Obligated this budget period
$802,428
24. Total Approved Cost Sharing or Matching, where applicable
$0
25. Total Federal and Non-Federal Approved this Budget Period
$802,428

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26. Project Period Start Date 05/16/2021 - End Date 04/30/2026
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period
$3,917,674

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Priscilla Grant
30. Remarks
Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH

Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I - AWARD DATA - 5R01MD015256-05 REVISED

Principal Investigator(s):
Brittany Michelle Charlton, DSC

Award e-mailed to: research_admin@hphci.harvard.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to HARVARD PILGRIM HEALTH CARE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD015256. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Priscilla Grant
Grants Management Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$246,010
Fringe Benefits	$68,883
Personnel Costs (Subtotal)	$314,893
Travel	$6,729
Subawards/Consortium/Contractual Costs	$260,235
Publication Costs	$5,000

Federal Direct Costs

$586,857
Federal F&A Costs
$215,571
Approved Budget
$802,428
Total Amount of Federal Funds Authorized (Federal Share)
$802,428
TOTAL FEDERAL AWARD AMOUNT
$802,428

AMOUNT OF THIS ACTION (FEDERAL SHARE)
$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (5) (for this Document Number)
AWARD NUMBER
TOTAL FEDERAL AWARD AMOUNT
5R01MD015256-05
$802,428

3R01MD015256-05S1
$99,998

TOTAL
$902,426

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)
YR
THIS AWARD
CUMULATIVE TOTALS

5
$802,428
$902,426

6
$801,979
$801,979

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
Payment System Identifier:
1042452600A1
Document Number:
RMD015256B
PMS Account Type:
P (Subaccount)
Fiscal Year:
2024

IC

CAN
2024
2025
MD
8472687
$802,428
$801,979

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CPS01PM / OC: 41025 / Released: 02/18/2025
Award Processed: 02/19/2025 12:03:40 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 5R01MD015256-05 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at
http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - STANDARD TERMS AND CONDITIONS - 5R01MD015256-05 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as
those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at
http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research

for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MD015256. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

· Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals,

see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

· For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

· HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.

· For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV - MD SPECIFIC AWARD CONDITIONS - 5R01MD015256-05 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

INFORMATION: This revised award's end date has been adjusted to 4/30/25 due to the large unobligated balance.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 05/30/2024 ALSO APPLY TO THIS AWARD:

INFORMATION: This revised award has been issued in accordance with NIMHD's Fiscal Year 2024 funding policy for non-competing awards.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 02/03/2024 ALSO APPLY TO THIS AWARD:

REQUIREMENT: This award is subject to the conditions set forth in PA-20-185, NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 05/05/20, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: The recipient is required to follow the data sharing plan included in the application and may not implement any changes in the plan without the written prior approval of the NIMHD.

INFORMATION: This award reflects the NIMHD's acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with NIH policy, "Required Education in the Protection of Human Research Participants," as announced in the June 5, 2000 NIH Guide (revised August 25, 2000) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html).

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

REQUIREMENT: Use of humans and animals in any new activities must be requested prior to the start of the activity and must be approved in writing in advance by the NIMHD. See NOT-MD-08-002, "Guidance and Clarification on NCMHD Policy on Prior Approval for Subprojects and Pilot Projects Involving Human Subjects or Vertebrate Animals," NIH Guide to Grants and Contracts, April 29, 2008, which is hereby incorporated by reference as special terms and conditions of this award. See also NOT-OD-15-129, "Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice," and NIH-OD-15-128, "Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice."

Copies of these Notices may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01MD015256-05 REVISED

INSTITUTION: HARVARD PILGRIM HEALTH CARE

Budget	Year 5	Year 6
Salaries and Wages	$246,010	$246,010
Fringe Benefits	$68,883	$68,883
Personnel Costs (Subtotal)	$314,893	$314,893
Travel	$6,729	$5,751
Subawards/Consortium/Contractual Costs	$260,235	$261,410
Publication Costs	$5,000	$5,000
TOTAL FEDERAL DC	$586,857	$587,054
TOTAL FEDERAL F&A	$215,571	$214,925
TOTAL COST	$802,428	$801,979

Facilities and Administrative Costs	Year 5	Year 6
F&A Cost Rate 1	66%	66%
F&A Cost Base 1	$326,622	$325,644
F&A Costs 1	$215,571	$214,925

EXHIBIT G

Fri, Mar 21, 2025 at 12:51 PM

Hi Brittany,

I'm sorry to forward the below termination notice for your R01.

Joe will be in contact with you to coordinate notification to subaward sites.

Cary

Cary Williams, MEd, CRA (she/her)

Director | Office of Sponsored Programs

Harvard Pilgrim Health Care, Inc. | Harvard Pilgrim Health Care Institute, LLC

617-867-4958 | cary_williams@hphci.harvard.edu

Upcoming OOO: 3/27 – 4/4

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 12:30 PM
To: Research Admin <research_admin@hphci.harvard.edu>
Subject: Grant Termination Notification

WARNING: This email originated from outside of the organization.
Do not click links or attachments **unless** you recognize the sender and know the content is safe.

National Institutes of Health
Office of Extramural Research

3/21/2025

Cary Williams

Harvard Pilgrim Health Care, Inc.

research_admin@harvardpilgrim.org

Dear Cary Williams:

Effective with the date of this letter, funding for Project Number 5R01MD015256-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 3/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, NIMHD

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf [grants.nih.gov].

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT H

Sexual and Gender Minority Populations in NIH-Supported Research

Notice Number: NOT-OD-19-139

Key Dates
Release Date: August 28, 2019

Related Announcements

- **September 6, 2024** - Updating the Definition of Sexual and Gender Minority Populations in NIH-Supported Research. See Notice NOT-OD-24-169.

Issued by
Sexual and Gender Minority Research Office (SGMRO)

Purpose

The purpose of this Notice is to announce the revision of the definition of sexual and gender minority (SGM) populations for research purposes at the NIH, as well as to provide a summary of information about SGM health research at the NIH. It is expected that this Notice will help to enhance the representation of SGM individuals in the agency's research portfolio and to stimulate the development of novel research projects and strategies to better understand and advance SGM health.

Implementation Timeline

This Notice is effective upon its release date.

The Sexual & Gender Minority Research Office

The NIH Fiscal Years 2016-2020 Strategic Plan to Advance Research on the Health and Well-Being of Sexual and Gender Minorities was released in 2015. The plan elucidated goals and objectives to encourage the advancement of basic, clinical, behavioral, population, and social sciences research to improve the health of SGM individuals. One of the objectives of the strategic plan was to establish a central office to coordinate SGM-related research and activities at the NIH. Established in 2015, the Sexual & Gender Minority Research Office (SGMRO) resides within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the NIH Office of the Director.

The NIH laid out four overarching goals in its FY 2016-2020 SGM strategic plan: (1) Expand the knowledge base of SGM health and well-being through NIH-supported research; (2) Remove barriers to planning, conducting, and reporting NIH-supported research about SGM health and well-being; (3) Strengthen the community of researchers and scholars who conduct research relevant to SGM health and well-being; and (4) Evaluate progress on advancing SGM research. The SGMRO pursues these goals by convening and participating in events involving SGM health priorities, managing dissemination of information about SGM health research, and working with NIH Institutes, Centers, and Offices (ICOs) to leverage resources and develop initiatives to promote SGM health and research.

Definition of Sexual and Gender Minorities

At the NIH, the term sexual and gender minority originally encompassed individuals who identify as lesbian, gay, bisexual, transgender, queer, or intersex, as well as those who do not self-identify with one of these terms, but whose sexual orientation, gender identity, or reproductive development varies from traditional, societal, cultural, or physiological norms. The NIH has heretofore opted to use this definition to maintain inclusivity and consistency in reporting. However, after consultation with several NIH groups that possess contemporary expertise in SGM health and research, the NIH is releasing an updated SGM definition to foster and expand

4/18/25, 9:23 PM Case 1:25-cv-10787-IT Document 1-95 Filed 04/25/25 Page 2 of 3

EXHIBIT I

Case: 25-1611 Case: 1:25-cv-10781-IT Document: 70-1 Filed: 04/25/2025 Page: 39 Date Filed: 04/25/2025 Page 83 of 97 Entry ID: 6736750

Recipient Information

1. Recipient Name
HARVARD PILGRIM HEALTH CARE INC
1 WELLNESS WAY
CANTON, MA 02021

2. Congressional District of Recipient
08

3. Payment System Identifier (ID)
1042452600A1

4. Employer Identification Number (EIN)
042452600

5. Data Universal Numbering System (DUNS)
071721088

6. Recipient's Unique Entity Identifier
NZVVQ8GNVX65

7. Project Director or Principal Investigator
Brittany Michelle Charlton, DSC
Assistant Professor
bcharlton@mail.harvard.edu
617-466-9262

8. Authorized Official
Charlotte Johnson
research_admin@harvardpilgrim.org

Federal Agency Information

9. Awarding Agency Contact Information
MICHELLE MAE Phillips
Grants Management Specialist
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
michelle.phillips@nih.gov
(301) 402-1366

10. Program Official Contact Information
Priscah Mujuru
Program Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
priscah.mujuru@nih.gov
301-594-9765

Federal Award Information

11. Award Number
3R01MD015256-05S1

12. Unique Federal Award Identification Number (FAIN)
R01MD015256

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Improving service delivery models of medically assisted reproduction: A patient journey mapping study of sexual minority women couples' experience of medicalized family formation

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
Supplement

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 03/01/2024 **– End Date** 02/28/2025	
20. Total Amount of Federal Funds Obligated by this Action	$99,998
20 a. Direct Cost Amount	$60,240
20 b. Indirect Cost Amount	$39,758
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$99,998
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$99,998
26. Project Period Start Date 05/16/2021 **– End Date** 02/28/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,917,674

28. Authorized Treatment of Program Income
Other (See Remarks)

29. Grants Management Officer - Signature
Priscilla Grant

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Version:25 - 2/15/2024 9:51 AM | Generated on: 9/4/2024 12:34 AM

A0849

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 3R01MD015256-05S1

Principal Investigator(s):
Brittany Michelle Charlton, DSC

Award e-mailed to: research_admin@harvardpilgrim.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $99,998 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to HARVARD PILGRIM HEALTH CARE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD015256. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Priscilla Grant
Grants Management Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$44,753
Fringe Benefits	$13,337
Personnel Costs (Subtotal)	$58,090
Other	$2,150
Federal Direct Costs	$60,240
Federal F&A Costs	$39,758
Approved Budget	$99,998
Total Amount of Federal Funds Authorized (Federal Share)	$99,998
TOTAL FEDERAL AWARD AMOUNT	$99,998
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$99,998

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (5) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3R01MD015256-05S1	$99,998
5R01MD015256-05	$802,428
TOTAL	**$902,426**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$99,998	$902,426
6	$0	$801,979

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1042452600A1
Document Number: RMD015256B
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
OD	8025139	$49,998
OD	8055775	$50,000

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CPS01PM / **OC**: 41023 / **Released**: 09/03/2024
Award Processed: 09/04/2024 12:34:35 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3R01MD015256-05S1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 3R01MD015256-05S1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MD015256. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Office Of The Director, National Institutes Of Health (OD)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment,

who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.

- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Other (See Remarks)

SECTION IV – MD SPECIFIC AWARD CONDITIONS – 3R01MD015256-05S1

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION: This supplemental award provides $50,000 funding from the NIH Office of Research on Women's Health (ORWH) and $49,998 from the Sexual and Gender Minority Research Office (SGMRO): These funds are restricted for this purpose and may not be expended for any other purpose without the written prior approval of the National Institute on Minority Health and Health Disparities.

REQUIREMENT: This award is subject to the conditions set forth in NOT-OD-22-032 and PA-20-272, Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional), NIH Guide to Grants and Contracts, 10/09/2020, which are hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: Use of humans and animals in any new activities must be requested prior to the start of the activity and must be approved in writing in advance by the NIMHD. See NOT-MD-08-002, “Guidance and Clarification on NCMHD Policy on Prior Approval for Subprojects and Pilot Projects Involving Human Subjects or Vertebrate Animals,” NIH Guide to Grants and Contracts, April 29, 2008, which is hereby incorporated by reference as special terms and conditions of this award. See also NOT-OD-15-129, “Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice,” and NIH-OD-15-128, “Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice.”

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects at any site engaged in such research for any period not covered by both (1) the awardee’s OHRP-approved Assurance

and if performance sites are involved, each performance site's OHRPapproved Assurance(s) and (2) appropriate IRB approvals consistent with all OHRPapproved Assurances.

Copies of these Notices may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

SPREADSHEET SUMMARY
AWARD NUMBER: 3R01MD015256-05S1

INSTITUTION: HARVARD PILGRIM HEALTH CARE

Budget	Year 5	Year 6
Salaries and Wages	$44,753	
Fringe Benefits	$13,337	
Personnel Costs (Subtotal)	$58,090	
Other	$2,150	
TOTAL FEDERAL DC	$60,240	
TOTAL FEDERAL F&A	$39,758	
TOTAL COST	$99,998	$0

Facilities and Administrative Costs	Year 5	Year 6
F&A Cost Rate 1	66%	
F&A Cost Base 1	$60,240	
F&A Costs 1	$39,758	

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EXHIBIT J

This notice has expired. Check the NIH Guide for active opportunities and notices.

Notice of Special Interest (NOSI): Administrative Supplements for Research on Sexual and Gender Minority (SGM) Populations (Admin Supp Clinical Trial Optional)
Notice Number:
NOT-OD-22-032

Key Dates

Release Date:

December 2, 2021

First Available Due Date:
January 31, 2022
Expiration Date:
February 01, 2024

Related Announcements

NOT-MD-22-007 - Notice of National Institute on Minority Health and Health Disparities (NIMHD) Participation in NOT-OD-22-032, NOSI: Administrative Supplements for Research on Sexual and Gender Minority Populations (Admin Supp Clinical Trial Optional)

PA-20-272 Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

Issued by

Sexual and Gender Minority Research Office (SGMRO)

National Human Genome Research Institute (NHGRI)

National Institute on Aging (NIA)

National Institute of Allergy and Infectious Diseases (NIAID)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

National Institute on Deafness and Other Communication Disorders (NIDCD)

National Institute of Dental and Craniofacial Research (NIDCR)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

National Institute on Drug Abuse (NIDA)

National Institute of Mental Health (NIMH)

National Institute of Neurological Disorders and Stroke (NINDS)

National Institute of Nursing Research (NINR)

Fogarty International Center (FIC)

National Center for Complementary and Integrative Health (NCCIH)

EXPIRED

National Cancer Institute (NCI)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of AIDS Research (OAR)

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention (ODP)

Office of Research on Women's Health (ORWH)

Purpose

The mission of the NIH is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The NIH is committed to supporting research that will increase scientific understanding of the health and well-being of various population and subpopulation groups and that will help to establish the effectiveness of evidence-based health interventions and services for individuals within these groups. NIH places high priority on research with populations that have distinct health risk profiles and who have also received insufficient attention from the scientific research enterprise. To this end, this Notice of Special Interest (NOSI) announces the availability of administrative supplements to provide funding for the expansion of existing research projects to incorporate sexual and gender minority (SGM) populations or SGM-relevant research questions. SGM populations include, but are not limited to, those populations described in NOT-OD-19-139. Basic, social, behavioral, clinical, translational, and health services research relevant to the missions of the sponsoring NIH Institutes or Centers (ICs) may be proposed in response to this solicitation. Potential applicants are encouraged to review the most recent annual Portfolio Analysis of NIH-funded SGM research to identify potential research gaps that may be relevant to this NOSI. More information about the SGM administrative supplements program and previously awarded research projects can be found on the SGMRO website.

Background

The collective knowledge base on SGM health has grown substantially since the release of the groundbreaking 2011 Institute of Medicine (now the National Academy of Medicine) report on the health of lesbian, gay, bisexual, and transgender people. However, in their comprehensive 2020 report on the status and well-being of people who identify as SGM, the National Academies Committee on Population ultimately concluded that SGMs still face numerous disparities across multiple domains of well-being. In October 2016, the National Institute on Minority Health and Health Disparities, in collaboration with the Agency for Healthcare Research and Quality, announced that SGMs had been officially designated a health disparity population for NIH research purposes. This designation has facilitated the creation of tailored research projects, programs, activities, and funding opportunities to tackle the unique health-related issues encountered by SGM individuals. In addition, ascertainment of SGM status in ongoing and planned population studies has been enhanced. However, it is apparent that SGM-specific health disparities persist today, and there is still an urgent need for novel strategies to understand, measure, address, and prevent them.

As of August 28, 2019, the NIH definition of "sexual and gender minorities" includes, but is not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, two-spirit, queer, and/or intersex. Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex. Applicants to this administrative supplement may propose to study relevant SGM subpopulations not explicitly identified in this definition and/or adopt other classification frameworks and terminologies as appropriate.

Specific Areas of Research Interest

This NOSI calls for research that will enrich scientific understanding of how sexual orientation, gender identity, and/or being born with differences/disorders in sex development (DSDs) or intersex characteristics relate to health outcomes, health risks, health behaviors, perceptions and expectations about health, and access to health-related services or associated barriers.

Appropriate topics or studies for these supplements may include, but are not limited to, those listed below:

- Addition of SGM participants to an ongoing study which either did not originally include them or has not enrolled enough SGM participants to make meaningful comparisons between groups; proposed studies must be sufficiently powered to allow for meaningful comparisons
- Expansion of an ongoing study focused on one SGM group to add another; proposed studies must be sufficiently powered to allow for meaningful comparisons
- Expansion of data collection (e.g., in surveys, questionnaires, etc.) to add items related to sexual attraction, sexual behavior, sexual identity, gender identity, gender expression, and/or non-binary sex when relevant and appropriate
- Secondary analyses of existing data to generate new information or hypotheses about SGM health
- Assessment of reliability and/or validity of measures relevant to sexual attraction, sexual behavior, sexual identity, gender identity, gender expression, and/or non-binary sex
- Methodological and strategic innovations to improve the recruitment and retention of SGM individuals in any research activity
- Expansion of prevention, screening, and wellness research tailored to SGM populations that aims to reduce health inequities
- Ethical, legal, or social science research on the implications of data collection and/or research findings on SGM populations

Scope of Support

Administrative supplements can be used to meet increased costs that are within the scope of the approved parent award, but that were unforeseen when the new or renewal application or grant progress report for non-competing continuation support was submitted. Applicants to this NOSI should propose research that, if successful, would contribute to a greater understanding of the health and well-being of SGM communities. Clinical trials cannot be proposed to be added to grants that do not include a clinical trial as that would constitute a change in scope.

IC-Specific Considerations

All applications submitted in response to this NOSI should fall within the mission of the IC of the awarded parent grant. Applicants are strongly encouraged to discuss their proposed supplement project with the IC Program Officer of the funded parent award prior to submission of a supplement application in order to ensure that the proposed activity aligns with the scientific priorities of the IC and is within the scope of the parent award. Scientific inquiries may also be addressed to the contacts listed in the Inquiries section below.

Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Please recognize that all SGM administrative supplement awards are made specifically for conducting the research proposed in each application. Progress reports specific to the SGM administrative supplement may be requested by SGMRO at any point. These progress report requests will be sent under separate cover from the Research Performance Progress Report. Unsatisfactory progress or reallocation of supplement funds to another purpose outside of the proposed research plan may lead to disqualification of participating programs from future consideration for this opportunity.

Application and Submission Information

Applications for this initiative must be submitted using the following opportunity or its subsequent reissued equivalent.

- PA-20-272 - Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

All instructions in the SF424 (R&R) Application Guide and PA-20-272 must be followed, with the following additions:

- Application Due Dates January 31, 2022 for FY 2022; January 31, 2023 for FY 2023; and January 31, 2024 for FY 2024, by 5:00 PM local time of applicant organization.
- The expiration date is February 1, 2024.

- The project and budget periods must be within the currently approved project period for the existing parent award.
- For funding consideration, applicants must include **NOT-OD-22-032** (without quotation marks) in the Agency Routing Identifier field (box 4B) of the SF424 R&R form. Applications without this information in box 4B will not be considered for this initiative.
- Requests may be for one year of support only.
- The project budget cannot exceed $100,000 in total costs.
- The Research Strategy section of the application is limited to 6 pages.
- The process for Streamlined Submissions using the eRA Commons cannot be used for this initiative.
- Applicants are strongly encouraged to notify the Program Officer at the IC supporting the parent award that a request has been submitted in response to this NOSI in order to facilitate efficient processing of the application.

Applications that do not comply with these instructions or are deemed otherwise non-responsive to the terms of this NOSI, will not be accepted for review.

Inquiries

Please direct all inquiries to the Program Officer associated with the parent award and/or the designated contact at the ICO supporting the parent award listed below:

Scientific/Research Contact(s)

Brad Newsome, PhD
Fogarty International Center (FIC)
Telephone: 301-496-1653
Email: brad.newsome@nih.gov

Inna Belfer, MD, PhD
National Center for Complementary and Integrative Health (NCCIH)
Telephone: 301-435-1573
Email: inna.belfer@nih.gov

Whitney Barfield, PhD
National Cancer Institute (NCI)
Telephone: 240-276-6170
Email: whitney.barfield@nih.gov

Tina L Gatlin, PhD
National Human Genome Research Institute (NHGRI)
Telephone: 301-480-2280
Email: gatlincl@mail.nih.gov

Melissa Gerald, PhD
National Institute on Aging (NIA)
Telephone: 301-496-3136
Email: melissa.gerald@nih.gov

Keith Crawford, PhD
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-669-2816
Email: keith.crawford@nih.gov

Heiyoung Park, PhD
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Telephone: 301-594-5032
Email: parkh1@mail.nih.gov

Richard A Jenkins, PhD
National Institute on Drug Abuse (NIDA)
Telephone: 301-443-6504
Email: jenkinsrj@mail.nih.gov

Carol B Hubner, PhD
National Institute on Drug Abuse (NIDA)
Telephone: 301-827-5926
Email: chubner@nida.nih.gov

Janet Cyr, PhD
National Institute on Deafness and Other Communication Disorders (NIDCD)
Telephone: 301-402-3458
Email: cyrj@nidcd.nih.gov

Dena Fischer, DDS, MSD, MS
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Email: dena.fischer@nih.gov

Vanessa A White, MPH
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Telephone: 301-827-5505
Email: vanessa.white@nih.gov

Beshaun Davis, Ph.D.
National Institute of Mental Health (NIMH)
Telephone: 301-827-5098
Email: beshaun.davis@nih.gov

Erica Littlejohn, PhD
National Institute of Neurological Disorders and Stroke (NINDS)
Telephone: 301-435-2719
Email: Erica.Littlejohn@nih.gov

Shalanda A Bynum, PhD, MPH
National Institute of Nursing Research (NINR)
Email: shalanda.bynum@nih.gov

Elizabeth L Neilson, PhD, MPH, MSN
Office of Disease Prevention (ODP)
Telephone: 301-827-5578
Email: Elizabeth.Neilson@nih.gov

Elizabeth Anne Barr, PhD
Office of Research on Women's Health (ORWH)
Telephone: 301-402-7895
Email: elizabeth.barr@nih.gov

Melissa Mera, MPH
Office of AIDS Research (OAR)
Telephone: 301-761-7689
Email: melissa.mera@nih.gov

Robert Freeman PhD
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Telephone: 301-443 8820
Email: Robert.Freeman@nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

EXHIBIT K

Fri, Mar 21, 2025 at 3:56 PM

Hi Brittany,

As you noted, the terminations continue. The supplement associated with the R01 has also been terminated.

Cary

Cary Williams, MEd, CRA (she/her)

Director | Office of Sponsored Programs

Harvard Pilgrim Health Care, Inc. | Harvard Pilgrim Health Care Institute, LLC

617-867-4958 | cary_williams@hphci.harvard.edu

Upcoming OOO: 3/27 – 4/4

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 12:35 PM
To: Research Admin <research_admin@hphci.harvard.edu>
Subject: Grant Termination Notification

WARNING: This email originated from outside of the organization.
Do not click links or attachments **unless** you recognize the sender and know the content is safe.

3/21/2025

Cary Williams

Harvard Pilgrim Health Care, Inc.

research_admin@harvardpilgrim.org

Dear Cary Williams:

Effective with the date of this letter, funding for Project Number 3R01MD015256-05S1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 3/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.**[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, NIMHD

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf [grants.nih.gov].

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

[redacted]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF KATIE EDWARDS

I, Katie Edwards, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am a Professor of Social Work at the University of Michigan. My research focuses on preventing sexual and related forms of violence among minority communities by using evidence-based, affirming, and culturally-grounded approaches. My current work is focused on program development and evaluation with Indigenous youth and communities, as well as LGBTQ+ youth. In 2024, I was named by Stanford University as one of the top two percent researchers in the world, and 26th out of 12,726 researchers in the field of criminology. In my lab, we have some of the first studies ever to show we have reduced violence and alcohol use among LGBTQ+ youth as well as sexual violence among Indigenous youth.
2. I am offering this declaration in my individual capacity and not on behalf of my employer.
3. My interest in this area of work began during my undergraduate studies. Through my studies and volunteer work, I saw the damaging effects of sexual violence and other forms of violence, and I wanted to learn how to prevent violence from happening in the first place. While most of my work in graduate school focused on college students, early on in my career as an assistant professor, I realized that most of the scientific literature at the time did not address the particular needs of LGBTQ+ youth, a glaring gap especially given that this demographic experiences disproportionately higher rates of sexual and other forms of

violence. My passion grew from wanting to work to help all youth who were experiencing these harms and especially youth experiencing high rates of violence about whom we as a field had done relatively less research.

4. Before working at the University of Michigan, I was a Professor of Educational Psychology at the University of Nebraska-Lincoln. Before that, I was an Assistant and Associate Professor of Psychology at the University of New Hampshire.
5. I received my B.S. in Psychology in 2005 from the University of Georgia. I completed my Ph.D. in Clinical Psychology at Ohio University in 2011, and I received a graduate certificate in Women and Gender Studies from Ohio University that same year.
6. To date, I have published more than 220 peer-reviewed journal articles, which were made possible, in part, through obtaining more than $23 million in research funding over the course of my career.
7. I have applied for and received 10 grants from the NIH over the course of my career. The application process for each grant was a lengthy and involved one, but that process—at least until recently—helped ensure that the most rigorous and impactful research is conducted. In my experience, preparing an application requires months, if not years, of work—from pilot studies, literature review or other background research, to input from community partners and fellow researchers, to honing methodological design—and often new studies will build off of the work and findings from previous studies.
8. Since March 2025, NIH has terminated at least six grants that fund research projects for which I am the principal investigator or co-investigator. For each of these grants, NIH stated in a termination notice that the project "no longer effectuates agency priorities." The total amount awarded originally across those six grants is approximately $11.9 million.
9. One of those terminated grants is a project-based R01 grant that was awarded on July 22, 2022. A true and correct copy of the notice of award (NOA) for that grant is attached hereto as Exhibit A. That grant—titled *An Innovative, Prospective Model to Understand Risk and Protective Factors for Sexual Assault Experiences and Outcomes among Sexual and Gender Minority Men* (Project Number 5R01MD016384)—originally had a total award value of over $3.8 million. *See id.*
10. Sexual assault happens more often to sexual minority men than to heterosexual men, but the scientific community has a limited understanding of why that disparity exists—and of how to

prevent sexual assault and support those who have experienced it among this community. The goal of this project was to use a rigorous methodology to focus on factors that predict sexual assault experiences among sexual minority men and trans-masculine people, as well as their recovery in the aftermath of those experiences. And more specifically, our goal was to use findings from this study to better understand how to reduce the risk of sexual violence experiences among sexual minority men and its negative outcomes, with the longer-term goal of developing programs and policies to address this public health crisis. Filling this gap in the literature and in public health is important because, among other reasons, an estimated 9.3% of the population identifies as LGBTQ+ (and more when looking at young people specifically), and because sexual violence is quite costly on society, with the Centers for Disease Control and Prevention (CDC) estimating that the lifetime cost of rape as $122,461 per survivor (a figure that includes medical care, lost productivity from work, and criminal justice costs). A true and correct copy of a screen capture of the CDC's website providing that estimated cost, last accessed April 24, 2025, is attached hereto as Exhibit B.

11. This project took the form of a survey administered over a two-year span. Each participant was supposed to take a baseline survey followed by a survey every six months (*i.e.*, a survey at six, 12, 18, and 24 months after the baseline survey). The survey at each time point asked largely the same questions, which sought information from the participants about experience with, among other things, sexual assault, alcohol consumption, discrimination, and mental health. While the baseline survey asked for information about a participant's entire past, each follow-up survey asked the participant for information that pertained to the six months since their prior survey. Each survey featured hundreds of questions and took participants on average 45 minutes to an hour to complete. Our hope was that analysis of the data collected across this two-year span and from 3,107 participants would ultimately provide guidance on interventions to prevent and respond to sexual violence among sexual minority men (many of whom were also racial/ethnic minorities) ultimately reducing health disparities and reducing high costs of sexual violence in the U.S.
12. I aligned this project with NIMHD's goals to advance the scientific understanding of health disparities and improve minority health.
13. A lot of time and effort went into the application for this project. My colleagues and I spent months immersing ourselves in the scientific literature, reading previously published

empirical and theoretical literature and drafting literature reviews on the subject matter—and ultimately coming to appreciate how little research existed at the time that was focused on how sexual violence specifically affects sexually minority men (especially for those identified as people of color). After reading and summarizing existing literature directly and indirectly related to sexual assault experiences among sexual minority men, we turned towards proposing a new theoretical model to understand why sexual violence happens among this population—a process that also took several months. The goal of that model was to make sense of the limited data already available, and to hypothesize what factors could affect the rate at which sexual minority men experience sexual assault as well as factors impacting their recovery. We developed ways to test this model and, after receiving feedback from colleagues, we drafted and submitted an application for funding to the NIMHD.

14. The application was referred to a study section group within NIH that consisted of a number of peer reviewers, including three peer reviewers specifically assigned to this application. That group provided feedback, but the NIMHD did not approve any award of funding, and we spent several months after that working on revising the application materials in light of and responding to that feedback. Those revisions included providing more information to support the proposed theoretical model, refining our methodology for collecting and analyzing data, and addressing a human subjects safety concern regarding data de-identification. We then resubmitted our application, which was again referred to a study section group of expert reviewers, three of whom were assigned to provide an in-depth and critical review of our grant. Following peer review that resulted in a fundable score, the NIMHD requested that we respond to a few remaining/minor matters, and we submitted a brief memo to address those remaining matters. Afterwards, our project was recommended for funding, and the notice of award was issued.
15. Since approving funding for this project, NIH has renewed this grant three times. NIH officials never raised any concerns with this grant during those renewal reviews.
16. There has been much progress in this study since NIH approved it. We have completed enrollment for the study, recruiting over 3,100 participants. Although the start date varies across participants, most participants are somewhere between their 18-month and 24-month

follow-up survey, with about 14% of individuals who have completed the entire span of the study. Data collection was set to wrap up in about a year.

17. Staff who work on this project were funded, at least in part, by this grant. For example, this grant pays a portion of my salary. A project coordinator for this project is fully funded by this project, and a project manager, a postdoctoral student, and part-time research assistants are partially funded by this project as well.
18. On March 11, 2025, an NIH official wrote me an email stating that "we're still working on it, ironing out things on our end," referring to a renewal and transfer of this grant.
19. But on March 12, 2025, NIH issued a notice terminating this grant. A true and correct copy of this termination notice is attached hereto as Exhibit C. Prior to this notice, there was never any indication that this grant was in jeopardy.
20. The termination notice does not include any individualized explanation for why the grant was cancelled and fails to discuss any of the data or analysis from our application, annual progress reports, or other related material. Instead, the termination notice includes the following language about its decision:

> This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Ex. C at 1.

21. On March 20, 2025, NIH issued a revised NOA reflecting the termination of the grant and echoing the language of the termination notice. A true and correct copy of the revised NOA is attached hereto as Exhibit D.
22. I do not understand what the notice or revised NOA means by the phrase "based on gender identity," and I do not understand why NIH believes this project is "based on gender identity." I also am uncertain why NIH believes this project does not effectuate agency priorities. I also do not know what the notice means by the term "biological realities."

23. This termination will severely hinder and may well completely preclude our ability to draw conclusions and develop recommendations from this study. As noted, most of the participants have yet to complete the entire course of the study. Although we are still conducting surveys for a limited time thanks to alternative funding sources, those sources are limited, and they will not last long enough to allow us to collect a full set of surveys for most—let alone all—of the 3,107 participants in this study. If, as forecasted, most participants do not have the opportunity to complete the final survey (or surveys for some participants), this will reduce the amount of data we can analyze including consistency of administrations across participants (a methodological flaw) in addition to limiting the statistical power of the analyses we are able to run. Collectively, these methodological and statistical issues will prohibit our ability to draw conclusions from the data we have collected and restrict the possible recommendations that can be developed to benefit sexual minority men (including racial/ethnic sexual minority men) across the U.S. That reduced ability to draw statistical inferences means that this area of research—and the populations served by this area of research—will not be able to benefit nearly as much as they would have, had funding for this project not been terminated. And this all assumes we even have someone to analyze the data we have collected: without sufficient additional funding, which at this time I do not anticipate securing, we will not have money to pay for an individual with the pertinent statistical background and expertise to analyze data. The funds for the statistician and her team to conduct rigorous study analyses were all terminated. That task alone requires months of data cleaning and weeks of running and refining complex statistical models.
24. Another grant that supports my research that the NIH terminated is a three-year project-based R34 grant originally awarded on October 12, 2023 by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). A true and correct copy of the NOA for that grant is attached hereto as Exhibit E. The total amount originally approved for this grant—titled *An Online Family-based Program to Prevent Alcohol Use and Dating and Sexual Violence among Sexual and Gender Minority Youth* (Project Number R34AA030662)—was $653,281. *See* Ex. E.
25. Based on work and findings by a prior NIH-funded project, my colleagues and I found that online intervention for LGBTQ+ youth reduced teen dating violence and alcohol use. From there, we thought it would be beneficial to better understand and develop programming that

would help not only LGBTQ+ youth but also their caregivers, as research shows that having a supportive caregiver also benefits LGBTQ+ youth tremendously. More broadly, the project also aims to facilitate family bonding and communications in addition to caregiver support and affirmation.

26. This project took the form of an online program with two groups: an experimental group and a control group. Participants in the experimental group would participate in a weekly online group intervention session for seven weeks, with separate programming for the participants who were sexual and gender minority youth (aged 15 to 18) and for their respective caregivers. Programming for caregivers focuses on increasing parental knowledge, acceptance, and support for their sexual and gender minority youth, as well as providing caregivers with evidence-based strategies focused on reducing risky behaviors among teens. Programming for sexual and gender minority youth focuses on reducing internalized stigma; enhancing social-emotional skills; increasing accurate perceptions of alcohol and dating violence norms; and increasing alcohol refusal skills. During the seven-week period that participants in the experimental group would take part in these sessions, individuals in the control group would receive periodic check ins but no similar programming. Before and after the seven-week period, we would conduct a survey for both the youth and their caregivers across both the experimental and control groups, to measure outcomes like frequency of dating violence and alcohol use and perceptions of trust or affirmation in the caregiving relationship.
27. In line with our understanding of our ethical obligations to all participants, at the completion of the seven-week period, we then offered all participants in the control group the opportunity to participate in the same programming in which the experimental group participants took part. But because there would be no comparable control group for these individuals during this subsequent seven-week period, no data would (or could) be meaningfully used from this intervention during that period to inform our understanding of how it worked.
28. My Co-Principal Investigators and I aligned this project with the goals of NIAAA to prevent alcohol abuse and related risk behaviors (such as dating violence) among diverse populations of youth.

29. As with the R01 grant described above, my colleagues and I spent months reviewing literature to prepare this application. Also, over the course of several months, we had to think very carefully about what a program for caregivers would look like, how to integrate that component, and how to go about this integration safely given the particular vulnerability of sexual and gender minority youth. Once we submitted the application, the level of rigor in the review process for this grant was similar to that of the R01 grant described above: our application was submitted to a study group, we did not initially receive funding and instead received feedback from the group, we worked for months refining the application, and after we re-submitted our grant application (along with a follow-up brief memo on any remaining issues flagged by the reviewers), NIH approved our grant.
30. NIH disbursed the total amount for this grant in its first disbursement. Still, we were required to submit annual progress reports. We have submitted one annual report, and the grant was renewed with no issues.
31. Staff who work on this project were funded, at least in part, by this grant. For example, this grant pays a portion of my salary, the salary of another PI, and the salary of a co-investigator. A project coordinator for this project is fully funded by this project, a graduate student, and part-time research assistants/program facilitators are partially funded by this project as well.
32. There had been a lot of progress on this study so far. We had designed the intervention program, conducted a pilot with one cohort of families, and started up the randomized control trial portion of the study. Our goal was to enroll around 80 families through the study, and we had already begun programming for the first cohort of participants—approximately 22 families (half in the experimental group, half in the control group). The rest of the participants would have participated in future cohorts.
33. But on March 21, 2025, NIH issued a notice stating that this grant was terminated. A true and correct copy of this termination notice is attached hereto as Exhibit F. Prior to this notice, there was never prior indication during the renewal process that this grant was in jeopardy.
34. The termination notice does not include any individualized explanation for why the grant was cancelled, and fails to discuss any of the data or analysis from our application, the annual progress report, or other related material. Instead, the notice includes the following language about its decision:

> This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Ex. F at 1.

35. On March 25, 2025, NIH issued a revised NOA reflecting the termination of the grant and echoing the language of the termination notice. A true and correct copy of the revised NOA is attached hereto as Exhibit G.

36. As with the termination notice for the R01 grant described above, I do not understand what the notice or revised NOA means by the phrase "based on gender identity," and I do not understand why NIH believes this project is "based on gender identity." I also do not understand why NIH believes this project does not effectuate agency priorities. I also do not know what the notice means by the term "biological realities."

37. This termination will hinder our ability to draw conclusions and develop recommendations from this study. As discussed, at the time the grant was terminated, we were in the middle of program interventions for the first cohort of participants. But because of this termination, we lacked the funding to ensure that we could complete the entirety of this cohort consistent with our ethical obligations to our participants—that is, the full seven weeks for *both* the experimental group and the control group, followed by seven weeks of intervention for those in the control group. As such, to abide by our ethical obligations, we were forced to prematurely begin interventions for the control group midway through the initial seven-week period. To draw meaningful conclusions from this study, the control group should have received the intervention after their final surveys. But because the termination forced us to prematurely begin the intervention for the control group, we can no longer use any of the data from this cohort for our analyses—at least not as intended with a comparison group. We also will not have statistical power to conduct analyses given that our sample size will fall short of what was proposed/intended. And at this time, we do not anticipate being able to secure sufficient additional funding to allow us to resume this study for future cohorts.

38. Since February 2025, NIH issued substantially similar termination notices or revised NOAs for four other grants that support my work, with the assertion that each "award no longer

effectuates agency priorities." Those projects are: 5R21MD018509 (*Development and Pilot Evaluation of an Online Mentoring Program to Prevent Adversities Among Trans and Other Gender Minority Youth*); 5R01AA031213 (*The Impact of Minority Stress on Alcohol-Related Sexual Assault Among Sexual Minority College Students: An Intersectional, Mixed-Methodological Study*); 5R01MD017573 (*Sexual Assault Recovery Among Sexual Minority Women: A Longitudinal, Multi-Level Study*); and R15 AA030898 (*Reconstruction of an SGM-specific Sexual Violence Peer Support Program [SSS+]*).

39. Every study is unique, and so the preparation of grant application materials will necessarily be unique, but the scale of the time, effort, labor, outreach, and scientific rigor was generally similar across all those grant applications. And yet, each of these termination notices failed to offer any individualized explanation of why the grant was cancelled and failed to discuss any of the data or analysis from our application, any annual progress report, or other related material. And because of the vague terms used across these termination notices, I am uncertain why the projects no longer effectuate agency priorities, how I can revise these projects to align with agency priorities, and how I can align future grant applications with these priorities.
40. Because of these terminations, projects and studies will be negatively impacted. My co-investigators and I will have an impaired—and in some cases, foreclosed—ability to complete studies, analyze any data collected, draw meaningful conclusions from that data, and develop recommendations to address health disparities experienced by vulnerable subpopulations—including sexual and gender minority individuals, LGBTQ+ youth, and people of color.
41. These terminations have and will continue to negatively impact our staff. For example, several staff have already been terminated, and more terminations are soon to happen because of a lack of funding resulting from the termination of these grants. These terminated grants funded part of my salary as well as the salary of other investigators on these grants. And much of our staff—from project coordinators and managers to graduate students to postdoctoral fellows to research assistants—were funded in large part through these grants. Absent additional funding, most if not all of those individuals will have severely reduced hours or will be completely terminated, and some are already terminated. For example, a postdoctoral fellow on these projects will now have their fellowship terminated in June. And

although my co-investigators and I are scrambling to secure replacement funding, that endeavor is taking away time from our current research, and I do not anticipate being able to secure nearly enough to secure the amount of funding (millions of dollars) that we would have had with those terminated grants.

42. On a personal level, I have never been more stressed in my entire life than I am now because of the impacts of these terminations. That stress has taken an emotional and physical toll, as the harms that have already resulted and will result from these cuts—to our staff, to our study participants, to the populations served by this research—have weighed on me each day. I regularly spend 15 or more hours a day trying to address the fallout from these terminations, from working on plans to ethically wind down studies; supporting staff and students who are distraught over losing work they are deeply passionate about and who are likely losing their jobs; and submitting to date over 20 grants/letters requesting funding to donors and nonprofit organizations (with no funding having been obtained to date). But I don't see how else to fund these programs besides through the now-terminated NIH grants.
43. Prior to March 2025, NIH had never terminated a grant that supported my research.
44. Appeals for three of the grants that support my research have been submitted. I anticipate that appeals for at least one of the other terminated grants will be submitted.
45. I supported submitting an appeal for each of these grants in large part because I do not anticipate being able to find replacement funding for the projects that fund them. But I still have no idea why the grants that support my research were terminated, and I had no idea how to address any agency concerns or recharacterize or revise my project for the purposes of appeal.
46. I also do not know whether the appeal has any chance of success, given the following language across the termination notices I received: "The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities."

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 24th day of April, 2025.

Katie Edwards

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF NICOLE MAPHIS

I, Nicole Maphis, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am a Postdoctoral Research Fellow at the University of New Mexico (UNM) and have been since June 2021. I have devoted my research career to understanding Alzheimer's disease and dementia due to my grandmother's diagnosis and slow submission to this awful disease. I have also pursued postdoctoral training in a lab focused on alcohol exposure to learn how consumption of excessive rates of alcohol could exacerbate the pathogenesis behind Alzheimer's disease. In the lab I mentor students, devise research projects, draft proposals and write manuscripts for publication. I have seven first author publications that explore tauopathy (which is the development of abnormal accumulations of a protein inside neurons, known as tau, seen within the brain of patients diagnosed with Alzheimer's disease and other types of dementia) and neuroinflammation [when the brain's immune system, e.g. microglia (a brain-resident immune cell) overreacts to brain pathology like amyloid beta plaques and tau tangles found in the brains of patients with Alzheimer's disease], and development of a potential immunotherapy to target tauopathy. In my postdoctoral work, I examine alcohol and its mechanistic impact on tauopathy as a risk factor for development or exacerbation of Alzheimer's disease.

2. I am the first person in my family to attend and graduate from college. I am from a low-income family and fit the criteria for a disadvantaged background as defined in Section C.7.(b) of the National Institutes of Health (NIH)'s Notice of Interest in Diversity because I grew up in a "Center for Medicare and Medicaid Services-designated Low-Income and Health Professional Shortage Areas." A true and correct copy of NIH's Notice of Interest in Diversity is attached as Exhibit A. Given these circumstances, I graduated from college with significant student loan debt. Following college, I worked as a technician/lab manager in two different research labs studying Alzheimer's disease for nearly 9

years before going to graduate school. During graduate school I focused my training on tauopathy and neuroinflammation and I developed and tested a patented immunotherapy.

3. I am offering this Declaration in my individual capacity and not on behalf of my employer.

4. From September 1, 2021–August 30, 2024, I was trained as a postdoctoral fellow within Institutional Research and Career Development Award (IRACDA) program at UNM, known there as Academic Science and Educational Research Training (ASERT). This distinguished national award provides salary and a small stipend to support education training and scientific research to educate and train the next generation of science educators, mentors, and scientific researchers. The unique aspects of this IRACDA program include that trainees are educated in a cohort-based model where four postdocs are hired together, take coursework on education pedagogy and other topics, like bioinformatics, leadership training, and attend monthly team-taught meetings. For example, I presented a lecture to the entire IRACDA group on choosing the right NIH awards based on one's goals. I also explained to my entire IRACDA group what a K99/R00 was and why I chose to apply for the MOSAIC K99/R00 award. IRACDA shaped my early career goals because of the detailed training and hands-on experience I gained at the partner institutions we worked with including Central New Mexico Community College (CNM), a nontraditional, Hispanic-serving community college, where I taught neuroscience lectures during the Anatomy and Physiology course. Other partner institutions where my cohort-mates taught included a 4-year undergraduate Hispanic-serving institution, New Mexico State University, and a 2-year indigenous college called Southwestern Indian Polytechnic Institute. Our IRACDA program focused on partnerships with majority minority-serving institutes (MSI) to broaden our experiences as well as enrich the lives and education of those students we taught. This IRACDA program helped train me to be a better educator and mentor, and to be more engaged with how education can be reframed to encompass and embrace cultural perspectives and "nontraditional" experiences.

5. I submitted my first MOSAIC K99/R00 to the PAR-21-271 for the deadline of February 12, 2024. I chose the MOSAIC (i.e. diversity mechanism) because I fit the criteria of a diverse candidate, being a woman, the first in my family to graduate college, and from a low socioeconomic family, but more so I wanted to apply to this program because I really excel in cohort-based models of career development, since I was trained in IRACDA (September 1, 2021–August 30, 2024). I also meet the qualifications of a MOSAIC candidate since I devote substantial time and efforts to DEI/STEM-related outreach including:

a. Teaching a neuroscience workshop at a summer camp for 7th grade girls

b. Helping to organize/host an outreach event called the New Mexico Brain Bee (a high school outreach event geared at getting high school students interested in neurosciences careers) for the last 10+ years

c. Helping teach numerous STEM outreach events geared at middle school populations including GoGirl Empowerment Seminar (Albuquerque, NM) and the Empowering Young Minds conference (Española, NM).

6. Excessive alcohol exposure throughout the lifespan can impact the risk of developing Alzheimer's disease and worsen the changes that occur in the brain of a person with Alzheimer's disease throughout the course of their disease. Recent human clinical studies point to excessive neural firing and the appearance of tau pathology as potential risk factors mediated by alcohol exposure, yet studies conducted in rodent models have yet to fully explain what is happening within the brain. Previous work from my lab has tested excessive alcohol use in a rodent tau model and found that those that consumed the highest level of alcohol had increased spread of tau, increased neuroinflammation, and increased issues walking, we also saw some mice exhibit a seizure phenotype. My proposal would have provided me with comprehensive training so that I could learn how to measure and describe how this excessive neural firing could potentially lead to the appearance and the spread of this harmful tau pathology. Nearly 7 million people are living with Alzheimer's disease, but only a small fraction (<5%) can be traced back to familial mutations that definitively cause the disease, which means that 95% of those with Alzheimer's disease, develop the disease sporadically. I, and many others, postulate that perhaps exposure to alcohol throughout various critical time periods of life (e.g. adolescence, early adulthood, middle age or advanced age) could prime the brain to develop Alzheimer's disease through either increasing neural activity (which is not always visible), and/or priming the brain to be more pro-inflammatory, both processes which could contribute to the appearance and the spread of tau pathology. If we understand the ways in which alcohol is doing this, then perhaps we can limit the impacts, or at least know that we need to prevent downstream consequences, like Alzheimer's disease.

7. In June 2024 I found out my initial MOSAIC K99/R00 application was ND (Not Discussed) by the assigned study group when they convened. ND is a common outcome for first-time applicants, as the process to get these awards is very difficult and time consuming. In fact, most individuals who go on to receive a K99/R00 end up having to revise and re-apply with their application. In fact, my primary research mentor and other co-mentors on my mentoring team received K99/R00 on their second submission. I then revised the initial application based on the feedback, provided in a document called a summary statement, by the three anonymous reviewers who are part of the -AA4 NIAAA study section.

I further revised my MOSAIC K99/R00 proposal based on the new PAR-24-225 and submitted it in time for November 12, 2024, deadline. A true and correct copy of PAR-24-225 is attached as Exhibit B.

8. I worked on this proposal approximately 8 hours/day, 3 ½ days/week over approximately 70 weeks from drafting the initial MOSAIC application draft (July 2023) and submission (February 2024), plus the process of the revision and editing and revising for the second submission (November 2024). This includes meeting with program officers to discuss the application and the revised application and meeting with mentors, reference writers, and my mentoring team to discuss the actual proposal, career development and training plan, as well as editing and updating other relevant documents like budget, biosketches, career development training plan, etc.

9. NIH has never provided me with any reason to expect that my MOSAIC grant application was in jeopardy. However, I had seen online that the program announcement to which I applied (PAR-24-225) was archived/closed two years ahead of its scheduled end date and that the MOSAIC program website was taken down, which were both disconcerting and led me to reach out NIH ahead of my scientific review.

10. On March 4, 2025, a Scientific Review Officer (SRO) at NIH emailed me to say: "Your application has been moved out of the AA-4 meeting while NIH undertakes a review of its research priorities under NIH's statutory and regulatory authorities. You should have received an automated message from eRA Commons about this. When or if the status of your application changes, you will receive additional notifications from eRA Commons." A true and correct copy of this email exchange, dated March 4, 2025, is attached as Exhibit C. I also discussed this by telephone with the same SRO approximately around the same time. During that conversation I asked, "Will my grant be reviewed?" The SRO replied: "Unfortunately not."

11. On March 14, 2025, a member of the study group assigned to evaluate my pending MOSAIC proposal, Dr. Patrick Mulholland, reached out to me on Bluesky (a social media platform) and said "these types of grants were removed from the discussion list for AA-4 on the morning of review. It's unclear to me if the SRO/PO will provide the written critique. My guess is that you won't receive anything until an official review. Hope that happens for you and the others very soon." A true and correct copy of Dr. Mulholland's message to me, dated March 14, 2025, is attached as Exhibit D. A true and correct copy of the Meeting Roster for the March 4, 2025, study section, showing Dr. Mulholland as Chairperson, is attached as Exhibit E.

12. On March 17, 2025, I followed up by email with my SRO and learned that "all review related data was deleted from the system when they moved the application out of the meeting." A true and

correct copy of this email exchanged, dated March 17, 2025, is attached as Exhibit F. I understand this to mean that I will not receive any feedback from the three reviewers who read and reviewed my pending application.

13. On March 25, 2025, I had a follow-up meeting with my PO who told me that I will not receive feedback, including comments on my application or the formal summary statement since it was not discussed at this study section meeting.

14. On March 21, 2025, I received a phone call from a member of the study section (-AA4) who confirmed that my grant was set to be discussed the morning of the discussion session. She went on to say that it was highly regarded and likely would have received funding had it not been for NIH's changes. She said "everyone was upset" that it was removed.

15. My MOSAIC K99/R00 does not differ from the parent award except for two documents:

a. The first is a "Statement on Activities to promote broad participation in biomedical research workforce" informally called a 'diversity statement.' This was previously known as the diversity statement on the original application, as shown by an earlier program announcement: PAR-21-271;

b. The second document the MOSAIC application requires that the parent track does not is a statement written and signed by the chair of my department to certify that I am a MOSAIC-eligible candidate and that I am dedicated to a career that champions and fosters DEI.

16. The delay in processing my application means I have run out of time to re-apply for this application. As described on page 6 of 25 in the announcement for this funding opportunity, the K99/R00 window is up to four years past the first day of your postdoc, which for me was June 1, 2021. A true and correct copy of PA 24-194 is attached as Exhibit G.

17. I sought and was granted an extension to apply to the parent K99/ROO for the June 12, 2025, deadline. However, the timeline for reviewing that application means that, even if I apply and secure funding, the funding will arrive too late for me to benefit from it. If I apply for the June 12 deadline, the proposal would not be reviewed until November 2025 and, if funded, the funding would not begin until March or April 2026. My fellowship, however, ends on September 30, 2025. A true and correct copy of an NIH webpage (last visited on April 16, 2025) showing standard due dates is attached as Exhibit H.

18. Because of NIH's refusal to consider my application, I have lost out on two years (the K99 phase of the award) where I would have received cutting-edge training on my four specific and unique training

goals that were detailed in the Career Development Plan included in my MOSAIC K99/R00 application. Those four goals, which rely on researchers from my mentoring team and my consultant to provide, are:

a. Intracranial implantation of custom-built Microwire electrode Arrays (MWA): Which would have allowed me to learn how to perform surgery on rodents to implant wires within the brain to record the electrical activity from within key regions of the brains altered by either alcohol and/or tauopathy. Not only would this training goal have helped to accomplish this research proposed, but learning this skill would have provided me with a very unique skill set to help secure a future faculty job.

b. Mathematical modeling/coding to measure brain activity: I would have been able to learn how to code the data and evaluate how the electrical activity within the brain is altered through this research training goal. This training would have built upon my limited knowledge base, helped accomplish the research proposed and ultimately help me secure a future faculty job with this skillset.

c. Learn how to infuse chemicals to alter brain activity: I would have learned how to implant specialized chemical compounds that can alter brain activity (excite/silence populations of neurons) to study how increasing or reducing electrical activity would have impacted brain activity within the brain. These skills would have helped to accomplish the goals of the research proposed as well as make me an attractive candidate for a future faculty job.

d. Perform experiments to induce alcohol dependence using alcohol using vapor chambers: This research goal would show me how to induce alcohol dependence within our models to understand how alcohol dependence and withdrawal can impact electrical activity, central to the research proposed. This goal would have helped facilitate the work proposed and increased my ability to get a faculty job.

19. I have also invested several months' assembling this MOSAIC application when I could have instead been focused on writing publications or drafting other proposals for consideration.

20. My institution (UNM) has lost out on the opportunity to train me for the next two years, and may not have the money to support my salary. UNM has also lost out on the indirect costs from the training portion (K99) of this grant, which is a percentage of the K99 award that is added to the overall award. The K99 portion was estimated to be $250,000 or $125,000/year for 2 years.

21. The T32 training program by which I am currently funded could potentially end on June 30, 2025. However, I have been assured through the mentor of the program that I will be eligible to be

carried forward until September 30, 2025. Still, I am constantly worried that this could fall through leaving me jobless by the end of June.

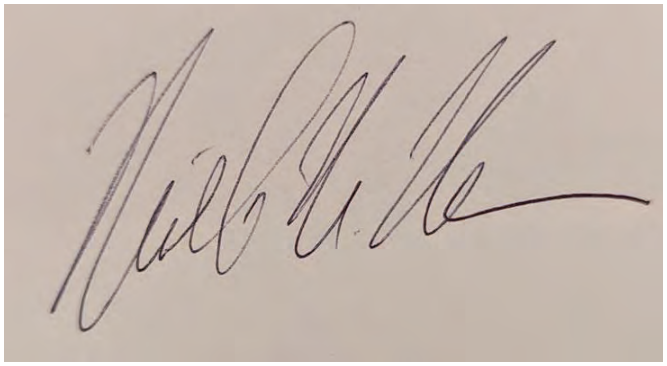
22. I have also lost out on the ability to receive the second phase of this award (the R00 phase), which is not only prestigious but would have provided me with approximately $750,000 ($250,000/yr for three years) towards launching my own independent research program at a future institution. I have potentially lost out on the opportunity to pursue this career path. More fundamentally, this also means I have potentially lost out on the ability to pursue a career path as a faculty member at a research intensive graduate or medical school, limiting my career trajectory. Finally, this also impacts my mentor, as having a postdoctoral fellow receive this award would have been beneficial to his career trajectory, too.

23. I have not been able to conduct any pilot projects related to this project nor lay any additional foundational work elucidating these mechanisms leaving this research undone and my progress towards research independence lacking.

24. The research that is now being shelved would have helped the public gain a more integral understanding of how alcohol use and alcohol use disorder could contribute to the development of Alzheimer's disease or the progression of this devastating disease, finding potential mechanisms and maybe even targetable pathways to reduce injuries induced by excessive alcohol consumption.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 20th day of April, 2025.



Nicole M. Maphis

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; and NICOLE MAPHIS *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, *in his official capacity as Director of the National Institutes of Health*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*, *Defendants*.	Case No. 1:25-cv-10787

DECLARATION OF PETER LURIE, MD, MPH

I, Peter Lurie, MD, MPH, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. I am the Executive Director and President of the Center for Science in the Public Interest, a 501(c)(3) nonprofit organization based in Washington, D.C. that advocates for improving public health through science-based policies and promoting scientific integrity.

2. I am offering this Declaration in my individual capacity and not on behalf of my employer.

3. I obtained a Bachelor of Arts Degree in Chemistry from Cornell University in 1982. In 1987, I obtained my Doctor of Medicine degree from the Albert Einstein College of Medicine, and I completed residencies in Family Medicine in 1990 and Preventive Medicine in 1992. I was an Assistant Professor of Epidemiology and Biostatistics and of Family and Community Medicine at the University of California, San Francisco from 1993-1998 and a Visiting Assistant Research Scientist at the University of Michigan Institute for Social Research from 1997-1999. I hold an adjunct faculty position at the Johns Hopkins School of Public Health and previously did so at the George Washington University School of Public Health and Health Sciences.

4. I have conducted research on HIV infection since the late 1980s. My main areas of interest are needle exchange programs, HIV vaccine trials, clinical trial ethics, HIV testing, the impact of foreign aid on the HIV epidemic, the epidemiology of HIV infection in developing countries, and post-exposure prophylaxis.

5. In the mid-1990s, I was the recipient of a grant from the National Institute of Drug Abuse to study the efficacy of needle exchange programs to prevent HIV infection. In 1998, I submitted a grant to the National Institute on Drug Abuse on the same topic, but it was not funded.

6. From 2014-2017, I was an Associate Commissioner at the U.S. Food and Drug Administration where I worked on a range of regulatory and analytical issues across the agency, including HIV pre-exposure prophylaxis and a potential switch to over-the-counter status for the opioid-reversal drug naloxone.

7. I was an advisor/consultant on an NIH-funded R21 grant titled "Over-the-Counter PrEP: Acceptability, Feasibility, and Potential Impact of Access without a Prescription (OFFSCRIPT)," which aimed to "evaluate the acceptability, feasibility, and potential impact of over-the-counter PrEP," or pre-exposure prophylaxis to reduce the risk of HIV transmission. The grant began on

July 1, 2024, and was a 2-year grant for $489,120. Of this, $277,552 was paid before it was terminated.

8. The Principal Investigators for this grant were Julia Marcus and Douglas Krakower, both of whom are Associate Professors at Harvard Medical School. Due to my decades of experience in HIV research and drug regulation, I was contacted by the Principal Investigators and asked to be an advisor/consultant on the grant and agreed to do so. In this role, I received and was to continue receiving a small amount of compensation under the grant for my services. I participated in some meetings about the grant.

9. The OFFSCRIPT grant was originally awarded based on an application responsive to a posting by the National Institute of Mental Health's Division of AIDS Research, which called specifically for projects that "advance innovative research to optimize HIV prevention and care."

10. The NIH-Wide Strategic Plan for Fiscal Years 2021-2025 lists thirty-five Bold Predictions, one of which is "NIH-wide research will lead to new implementation strategies for pre-exposure prophylaxis that will significantly reduce the number of new HIV infections and to new longacting therapies to improve viral load suppression among people with HIV to levels that prevent transmission." *See* Ex. A, NIH-Wide Strategic Plan for Fiscal Years 2021-2025, at 35, Bold Prediction no. 15.

11. The OFFSCRIPT grant scored in the top 3% of applications during the NIH review process and was funded in part by Innovation Funds from the NIH Office of the Director.

12. However, on March 21, 2025, the grantee institution received a notice from NIH stating that the OFFSCRIPT grant had been terminated. That letter asserted that the award "no longer effectuate[d] agency priorities" and stated that the basis for termination was that the grant was "based on gender identity." At no time before receiving this termination letter did I or the

Principal Investigators receive any notice that this grant was being considered for termination. In addition, no guidance was provided about how to close out the study and how to manage study participants who had already agreed to participate.

13. Despite the assertions in the termination letter, in actuality, the OFFSCRIPT grant was not "based on gender identity," but rather focused on the efficacy of increasing access to preventative HIV drugs for all patients. Though the grant plan included an assessment of "diverse cohorts of cisgender MSM [men who have sex with men], transgender women, and cisgender women on interest in use of OTC PrEP," such an assessment is a necessary tool to evaluate the potential impact of expanding access to PrEP on the population groups most likely to benefit from it. It was not the grant's primary purpose. To my knowledge, this is the first grant to ever look at OTC PrEP.

14. I found the termination letter vague. I do not know exactly what makes a research project to be "based on gender identity," or which NIH priorities this award "no longer effectuates." Similarly, due to the vagueness of the termination letter, I do not know what public health topics might be funded by NIH in the future. Even though I understand that an administrative appeal will be filed concerning this termination, this is likely to be a futile exercise.

15. There were three main study aims, described in this paragraph, and we were mid-way in making progress on these study aims. First, we were in the midst of collaborating with others who had appropriate cohorts to assess subjects' interest in PrEP. Second, we had begun conducting interviews with key stakeholders on attitudes toward PrEP and were starting to analyze those transcripts. Third, we had built a mathematical model to estimate the impact of OTC PrEP on new HIV infections and relevant safety outcomes. As a result of the termination of this grant, work on all three of the study aims was largely stopped.

16. In addition, before the termination, we presented preliminary research at a national conference and were preparing a manuscript describing our findings.

17. As a result of the termination of the OFFSCRIPT grant, the research into PrEP access being conducted under the grant has been largely discontinued, resulting in harms to public health in the form of reduced knowledge about how to effectively reduce the spread of HIV. This is a loss to the American public because PrEP is highly effective but greatly underutilized, a gap this research might have bridged.

18. I will no longer benefit from either financial disbursements under the grant, nor will I be able to conduct the work I set out to complete in assisting in the evaluation of potential HIV prevention measures, a topic of great personal and professional interest to me given my decades of research on HIV and AIDS prevention.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 7th day of April, 2025.

Peter Lurie

Peter Lurie, MD, MPH

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; and NICOLE MAPHIS, Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, *in his official capacity as Director of the National Institutes of Health*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of the United States Department of Health and Human Services*, et al., Defendants.	No. 1:25-cv-10787-BEM

DECLARATION OF GEORGES C. BENJAMIN, M.D.

I, Georges C. Benjamin, do hereby state the following, pursuant to 28 U.S.C. § 1746:

1. I am the Executive Director of the American Public Health Association (APHA). I have served in that role since December 2002.

2. APHA's mission is to: "Build public health capacity and promote effective policy and practice." APHA members include more than 23,000 individual public health professional members, as well as agency members such as organizations interested in health, state and local health departments and health related businesses. APHA also coordinates with state and regional APHA affiliates across the nation. APHA members work in every discipline of public health, in

every state, and in countries across the globe.

3. I make this declaration on behalf of the American Public Health Association in support of its motion to enjoin the National Institutes of Health and the Department of Health and Human Services from implementing or enforcing its directives forcing agency administrators to terminate the federal grants funding APHA's members' critical research.

4. I am a graduate of the Illinois Institute of Technology and the University of Illinois College of Medicine. I am licensed to practice medicine in Maryland and the District of Columbia. I am board-certified in internal medicine and a Master of the American College of Physicians, a fellow of the National Academy of Public Administration, a fellow emeritus of the American College of Emergency Physicians, an elected member of the National Academy of Medicine (formally the Institute of Medicine) of the National Academies of Sciences, Engineering and Medicine, an honorary fellow of the Faculty of Public Health, and an honorary fellow of the Royal Society of Public Health.

5. Following graduation from medical school, I entered active duty in the Army where I completed a residency in internal medicine at the Brooke Army Medical Center in San Antonio, Texas. Upon completion of my residency in 1981, I was assigned to Madigan Army Medical Center in Tacoma, Washington, as faculty and staff in the Department of Emergency Medicine, there I managed a 72,000-patient per year ambulatory care service as chief of the Acute Illness Clinic and was an attending physician within the Department of Emergency Medicine. I was reassigned in 1983 and from then until the spring of 1987, I served as chief of emergency medicine at the Walter Reed Army Medical Center.

6. Following my discharge from the United States Army in 1987, I was appointed as Chair of the Department of Community Health and Ambulatory Care at the District of Columbia General Hospital, serving in that post until December of 1990. From January 1990 to the fall of

1991, I was the Acting Commissioner for Public Health for the District of Columbia, and the Acting Director of the Emergency Ambulance Bureau in the District of Columbia Fire Department. I returned to serve as the Intermin Director of the Emergency Ambulance Bureau from the fall of 1994 to the spring of 1995.

7. I served as the Secretary of the Maryland Department of Health and Mental Hygiene from April 1999 to December 2002, following four years as its Deputy Secretary for Public Health Services.

8. In April 2016, I was appointed by President Obama to the National Infrastructure Advisory Council. In that role, I helped advise the President on how best to assure the security of the nation's critical infrastructure. I served in this capacity until December of 2020.

APHA's Mission, Structure, and Activities.

9. The mission of public health is to "fulfill society's interest in assuring conditions in which people can be healthy."[1] Public health has been defined as "the science and art of preventing disease, prolonging life, and promoting health and efficiency through organized community efforts and informed choices of society, organizations, public and private communities, and individuals."[2]

10. As a discipline, public health involves:

a) identifying health issues and priorities through the study of communities and specifically through a focus on at-risk communities

b) shaping public policies and interventions to address national, regional, and

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[1] Institute of Medicine, The Future of Public Health. National Academy Press, Washington, DC, 1988.

[2] Winslow, C.E.A. (1920). The untilled fields of public health. Science, 51(1306), 23-33.

local concerns, and

c) ensuring all populations have access to appropriate and affordable health and disease prevention services as well as monitoring and evaluating those services and care.

11. The American Public Health Association was founded in 1872, at a time when scientific advances were helping to reveal the causes of communicable diseases. These discoveries laid the foundation for the public health profession and for the infrastructure to support APHA's work. Since that time, public health has evolved into a broad health discipline involving several different types of practitioners.

12. APHA members work in every discipline of public health, in every state in the country, and in countries across the globe. APHA members are united with a common goal to promote optimal, equitable health and well-being for all.

13. From its inception, APHA has been dedicated to ensuring optimal health of all U.S. residents. Two of its most important functions have been advocacy for adoption by the government of the most current scientific advances relevant to public health, and public education on how to improve individual and community health. Along with these efforts, APHA has also campaigned for developing well-organized governmental health departments at the tribal, federal, state, and local levels to provide the governmental level role to fulfill its statutory obligations.

14. APHA works with key decisionmakers to shape public policy to address today's current and emerging public health concerns. Those include ensuring access to care, protecting, and increasing funding for core public health programs and services and eliminating health disparities. APHA is also working on other critical public health issues including public health and emergency preparedness, food safety, hunger and nutrition, and the full range of

environmental health issues, public health infrastructure, disease control, international health, and tobacco control.

15. APHA also produces statements and resources for public health practitioners, including member-developed policy briefs that provide evidence to use in public health education and advocacy, provide easy access to the latest research and findings in public health, and assist policymakers and regulators in being able to access up-to-date facts and findings as they relate to public health. APHA holds an annual convention, the largest of its kind in public health, where students and published academics alike can present their research and learn from one another.

16. Among an array of other scientific literature, APHA publishes *The American Journal of Public Health*, which is dedicated to publishing ***original*** work in research, research methods, and program evaluation in the field of public health to advance public health research, policy, practice, and education.

Equity and Inclusion are Central to APHA's Activities and the Activities of Its Members

17. The entire field of public health is dedicated to an understanding of and creating interventions to ensure optimal health for all. This includes addressing inequitable access to health and health-related services and to achieve equity in health status. This type of work is essential not only to APHA's own mission but to the discipline of public health itself and society as a whole.

18. APHA and its members work on initiatives to ensure that health and health services are accessible to people in all communities. APHA and its members also study and research the way in which disease, injury, or health related issues affect populations that have been marginalized and excluded from full participation in society or that face resource deficits. Seeking to bring about optimal health through the appropriate distribution of health resources,

ensuring that all communities have access to preventative health services and health care, and understanding the social determinants of health—the way in which nonclinical socio-economic factors, geographic factors, public policies and demographics that affect health-related outcomes—are all central to the field of public health and to the work of APHA and its members.

19. APHA has several programs and activities aimed at eliminating discrimination and exclusion in the provision of health services including prevention and ensuring that the public is educated about both overt discrimination and bias. Its members also are individually and collectively engaged in this work.

20. APHA is involved in and supports research focused on addressing structural racism and developing solutions to mitigate racism within the institutions, including health institutions, in the United States. Many of APHA's members also, individually and collectively through APHA, take part in similar initiatives. For some of these members, such research is not just another component of their work, but the very foundation for their careers.

APHA's Members Rely on NIH Grant Funding for their Work

21. APHA members rely heavily on funding from the Department of Health and Human Services, and from NIH in particular. NIH grants are essential to our members' ability to support a wide range of activities, from tribal, federal, state, territorial and local health departments, to community-based programs, to academic research. APHA members have reasonably relied on the continued receipt of NIH grants that have already been awarded and, in general, on the continued availability of NIH grants to support work that is consistent with congressional mandates of the agency to conduct medical research and protect public health.

22. Accordingly, the indiscriminate termination of grants by the NIH has already severely impacted our members' work by disrupting ongoing programs and community support, making it difficult – if not impossible – to plan for the future. It has directly harmed individuals

whose jobs are supported by this funding, both direct grant recipients and those whom they employ. And if allowed to continue unabated, these terminations will have a severely negative impact on public health.

Partisan Political Considerations Jeopardize Public Health Initiatives

23. APHA members need the flexibility to pursue their work without fear of persecution or disruption in response to emerging threats to public health. Otherwise, precious time will be wasted, and lives will be lost. Such impacts of political pressure on public health are not hypothetical.

24. Congressional action in the 1990s prohibiting federal funds from being used to "advocate or promote gun control" effectively chilled public health research into firearm injury prevention and its effect on communities for decades, as researchers feared having their work shut down if outside groups regarded it as advocacy. Even after the initial language was clarified, it still took years for Congress to expressly allow for funding to be reappropriated and for agencies to feel free to properly investigate a critical public health concern. Firearm injury disproportionately impacts communities of color with African American men receiving the bulk of the injuries and deaths. Firearms are also the leading cause of death for all children and teens regardless of race or ethnicity.

25. Conversely, the history of American public health has demonstrated the importance of continuing research that examines disparate outcomes in marginalized communities, even in the face of partisan pressure not to study these groups. The AIDS epidemic, for instance, required researchers to pay careful attention to racial, gender, and sexual orientation differences in high-risk populations to develop effective interventions for particular communities to slow the spread of the virus. In the absence of such tailored responses, HIV and other sexually transmitted diseases would have wrought considerably more damage among these groups and to

the general population.

26. As a more recent example, the rapidly evolving response to the COVID-19 pandemic also required researchers to quickly account for the needs of different communities, particularly regarding vaccine skepticism among ethnic minorities, some who were directly targeted with misinformation to sow distrust among ethnic minorities. By paying careful attention to these differences, researchers were able to guide authorities to direct resources and tailor responses accordingly, especially regarding vaccine distribution, benefiting the broader population as a result.

27. When researchers are empowered to do their work free from political pressure, public health benefits. When they are discouraged, public health suffers.

APHA Members Have Had Their Projects Cancelled Without Fair Warning

28. Since at least February 2025, NIH has informed APHA members with previously awarded grants – some of which had been in place for years – would be terminated. Others have been informed, either directly or indirectly, that grant proposals they had already submitted would not be considered. These members were informed that these curtailed grants and programs "no longer effectuate agency priorities." Specifically, the NIH targeted projects that dealt – however remotely or tangentially — with "gender identity" (also characterized in grant termination letters as "transgender issues"), and "diversity, equity, and inclusion" or "DEI."

29. Grant recipients were given no particularized justification for why their projects were canceled, or how their projects suddenly failed to "effectuate agency priorities." Instead, they all received the same cut-and-paste response based on the category highlighted by the new directives that their project was judged to deal with.

30. Prior to the recent waves of terminations, I have never been aware of an APHA member having their NIH grant terminated.

31. I am aware of one dues-paying APHA member, who I will refer to as APHA Member 16, who is a named professor at a major private research university. As part of their work, APHA Member 16 has prioritized mentoring and training the next generation of scientists. To do this, they lead NIH-funded programs that have supported training in STEM fields at multiple levels, spanning from undergraduate students to graduate students and post-doctoral scholars.

32. Member 16 was awarded an NIH grant in excess of $600,000 to run a MARC program at their university, with an award term of five years. The goal of the MARC Program, as described in NIH PAR 21-147, is to develop a diverse pool of undergraduates who complete their baccalaureate degree, transition into, and complete bio-medical, research-focused higher degree programs. The MARC program is limited to applications from training programs at baccalaureate degree-granting research-intensive institutions, defined as those that receive an average of $7.5 million per year in NIH funding over the previous three fiscal years. A true and correct copy of the PAR is attached as Exhibit A.

33. MARC awards are part of the NIH Ruth L. Kirschstein National Research Service Awards (NRSA) program, which has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. The PAR explains that these awards are designed to address the NIH's recognition of the "need to diversify the scientific workforce by enhancing the participation of individuals from groups identified as underrepresented" in biomedical research workforce.

34. Based on extensive data to support this definition, NIH describes the benefit of diverse teams as follows:

> Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual interests to address complex scientific problems. There are many benefits that

> flow from a diverse NIH-supported scientific workforce, including fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of research, enhancing public trust, and increasing the likelihood that health disparities and the needs of underserved populations are addressed in biomedical research.

35. Despite NIH's longstanding efforts to diversify the biomedical field, underrepresentation continues to be a problem. The PAR provides citations to support that fact that:

> Individuals from certain groups and backgrounds are underrepresented in the biomedical sciences research workforce as described in NIH's Interest in Diversity. The severity of the underrepresentation of these groups increases throughout the training stages. For example in 2017, students from certain racial and ethnic groups, including Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders comprised ~35 percent of the college age population, but earned only ~25 percent of bachelor's degrees and ~16 percent of Ph.D. degrees in science and engineering. Additionally, while the United States has seen a significant increase in the number of Ph.D. degrees in the biomedical sciences earned by scientists from groups underrepresented in the biomedical research workforce, a corresponding increase in the ranks of the faculty in basic science departments at medical schools has not occurred.

36. According to NIH, diversity enhancing institutional training grants to offset the cost of appointed trainee stipends, tuition and fees, and training related expenses, including health insurance, along with provision of activities that build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members have been proven to increase persistence in STEM fields.

37. APHA Member 16 has witnessed the importance of such grants to strengthen the scientific community. Over the years, they have seen many students who were able to gain research experience due to support from NIH institutional training grants who have benefited immensely. They have seen numerous examples of students who were the first in their family to go to college or came from families with very limited financial means, who are now completing residency training in critical fields such as neurosurgery and oncology, MD/PhD degrees to

develop into physician scientists, and PhD degrees in many different fields. Many of these students might never had access to research opportunities without such programs because they would have needed to work to pay for their tuition and/or living expenses. As APHA Member 16 has witnessed, these institutional training grants provide equitable access to research so students with different levels of financial means can understand what it takes to develop the skills to become a member of the biomedical workforce.

38. I understand that applying for a MARC grant is a difficult process. I am told the final proposal was comprised of ~500 pages of information required to evaluate the plans to train undergraduate students who have the goal of pursuing a PhD or MD/PhD.

39. I understand that once a MARC application is completed, it is submitted to NIH and considered for rigorous review by a team of peer reviewers (faculty at other institutions) on the NIH study section that reviews such training and workforce development proposals. Most of these faculty member peer reviewers run similar NIH-funded programs at their own institute, so are very familiar with these programs. The review is very rigorous, with three assigned reviewers tasked to read the entire application and comb through all the data tables to assess the rigor and potential impact of the planned training.

40. APHA Member 16 was awarded the MARC grant in spring of 2023 with an Impact Score of 25. They successfully sought a non-competitive renewal in 2024 and submitted a second non-competitive renewal application by the deadline of October, 2024. They expected that they would receive another non-competitive renewal in 2025. The non-competitive renewal process is significantly less onerous than a competitive NIH application. For the non-competitive renewal, PIs assemble a report of Major Accomplishments, including a report for each supported trainee, including the degree sought, the research mentor, a brief description of the research project, courses taken, conference presentations, contributions to manuscripts,

awards, and professional development activities. The report also includes plans for the next reporting period to accomplish the goals of the application as well as an Outcomes table detailing the trajectory of all supported MARC students, including any terminal degree received, position or training following the terminal degree and subsequent fellowships.

41. APHA Member 16 completed this report in anticipation of renewing their MARC grant. They have never heard of a non-competitive renewal being denied in their nearly 30 years of experience with NIH grants.

42. On April 2, 2025, APHA Member 16 received an email from NIH terminating the MARC grant. A true and correct copy of the email, redacted to remove all identifying information, is attached hereto as Exhibit B.

43. The email states "due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions. We advise against recruiting future cohorts." No further explanation for the termination was provided.

44. The termination has significant impacts on the students being supported, the university hosting them, and APHA Member 16.

45. During the first two years of the grant, APHA Member 16's work included organizing a 1-hour class that the funded MARC scholars attended weekly to support their scholarly and professional development. They also met regularly with each funded scholar and provided detailed feedback on applications to attend summer research programs, for graduate school, for MD/PhD Programs, for post-baccalaureate research opportunities, and many other internship opportunities. APHA Member 16 organized numerous mock interviews as well as

activities beyond the classroom to build a supportive cohort, such as weekend walks at various outdoor locations. A large fraction of the cohort also attended and presented their research at the Annual Biomedical Research Conference for Minoritized Students (ABRCMS) in both Year 1 and Year 2 of the MARC program. Two of the students won awards for their outstanding presentations at these meetings each year.

46. The MARC students rely on MARC funding to pay their tuition. Without the tuition assistance provided by the MARC award, students may incur additional student loan debt because they were awarded $16,000 in tuition funds as a MARC Scholar. The MARC grant also provided an annual research stipend in the amount of $14,340 per year for junior and senior years as of June 2024. This annual stipend allowed students to accept summer research opportunities and to focus on research opportunities during the academic year rather than paid employment. APHA Member 16 is very concerned that these students, many of whom are of low socio-economic status, will now lose access to research opportunities, as they will need to seek other paid positions to pay for tuition, food, and housing.

47. The university will also be injured by the loss of this workforce and the impact that the loss of funding has on critically important research, including end stage liver disease, development of new antimicrobial drugs to combat antibiotic resistance, and skin cancer. These are just a few of the areas current MARC students have contributed to, which will now be impacted by the loss of funding for these individuals and the need for the MARC students to seek other employment.

48. The MARC termination has not only impacted APHA Member 16's salary; it has also affected their professional credentials. Obtaining and maintaining NIH funding is an important aspect of demonstrating one's success in the biomedical field. And the mentoring and training work APHA Member 16 has done, made possible by NIH funding and recognized

through several prestigious awards, is part of the value they bring as a faculty member to their university.

49. APHA Member 16 considered sharing their story publicly, but has declined to do so out of fear that disclosure of their name will lead to retaliation against their university in the form of additional terminated federal grants and the withholding of future federal funding.

50. Another similar program to MARC is the Initiative to Maximize Student Development (IMSD) program. The goal of the IMSD Program, as described in NIH PAR 21-025, is to develop a diverse pool of scientists earning a Ph.D. and who have the skills to successfully transition into careers in the biomedical research workforce. The IMSD program is limited to applications from training programs at research-intensive institutions, defined as those that receive an average of $7.5 million per year in NIH funding over the previous three fiscal years. A true and correct copy of the PAR is attached as Exhibit C.

51. Like MARC awards, IMSD awards are also part of the NIH Ruth L. Kirschsten National Research Service Awards (NRSA) program, described in paragraph 33, above, and serve the same goals and interests. Whereas MARC awards are used to support undergraduate students interested in pursuing higher degrees in bio-medical research, IMSD awards are used to support graduate students as they transition into to graduate training, with the goal of ensuring that they successfully complete their PhDs, creating a stronger biomedical workforce of individuals with advanced degrees.

52. I am aware of an APHA Member who has received multiple IMSD awards from NIH. Their most recent award was in excess of $1,020,000, for winter 2023 through winter 2028.

53. This APHA Member received an email from NIH on April 2, 2025, terminating their IMSD grant. A true and correct copy of the email, redacted to remove all identifying information, is attached hereto as Exhibit D.

54. The email states "due to changes in NIH/HHS priorities, the **Initiative for Maximizing Student Development (IMSD)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions. We advise against recruiting future cohorts."

Harms to APHA Members

55. These experiences are not unique. In the few weeks since NIH issued this new guidance, I have also heard from numerous APHA members expressing concerns about being able to continue research in their chosen area of study based on the termination notices they have received from NIH. These include, for example, terminations of research projects to improve prevention strategies and care for HIV, to help young adults to resist tobacco marketing, and to better reach vulnerable populations. For some members, like those who study minority health or health disparities—a subject to which NIH has a whole institute devoted—the change in NIH priorities means an end to their research careers, for all intents and purposes.

56. I have also heard from APHA members that they are unable to develop new proposals to address pressing public health issues which they reasonably fear will be immediately struck down as inconsistent with NIH's new priorities. APHA members have also articulated fears that they will have to change specific words in their proposals so as not to be flagged for impermissibly promoting DEI in violation of NIH's new priorities. But given the vagueness of the NIH's guidelines—which do not define terms such as "Diversity, Equity, and Inclusion" or "DEI", "amorphous equity objectives," "Transgender issues," "gender identity," and "COVID-related research" while forbidding research "based on" these topics—they do not know how drastic their edits should be, or if any edits would satisfy NIH's scrutiny of certain projects.

57. Aside from the immediate aftershocks this has had on APHA members' ongoing work, NIH's new directives also jeopardize their future plans. There are APHA members who have spent countless hours crafting grant applications that the NIH now outright refuses to consider, and others who exist in limbo, unsure if they will ever be able to submit an application on their areas of study in the future.

58. And aside from the scientific harms imposed by NIH's misguided stance, the directives are also a discriminatory imposition on APHA members' freedoms of speech, inquiry, and association.

59. By categorically banning any study related to what it considers "diversity," "equity," "inclusion," NIH is signaling to the APHA members and the broader scientific community alike that any study that incorporates these elements – however tangentially, and in whatever form – is intrinsically disfavored and will be subject to harsher scrutiny from the federal government.

60. Further, studies that rely on public participation are jeopardized. If would-be grant recipients examine and account for the demographic differences among respondents, they run the risk of having their projects terminated under the new NIH guidelines— despite the fact that accounting for these differences is critical in order to properly fund educational initiatives and federal health care programs such as Medicare and Medicaid. Indeed, even if a study focuses on a homogenized minority population, they risk termination if that population is judged to be invoking "DEI" principles. Given the separate directive on "gender identity," this scrutiny is especially intensified if the study focuses on or even acknowledges the existence of LGBTQ people, and transgender people in particular.

61. As a direct result, APHA researchers are forced to choose whether to continue with important research that is supposedly no longer in accordance with NIH's priorities and risk

losing their funding, or to cancel any research that deals with racial, sexual, gender, or ethnic minorities in order to retain it.

62. The longer this guidance is in effect, the longer of an impact it will have on individual researchers as well. Interruptions in research can result in loss of research staff as well as unrecoverable delays in students' academic pursuits, potentially with additional financial costs incurred as a result of prolonging their studies while looking for additional support. It would be even worse for faculty members, who can lose years of valuable progress in their career if their studies are interrupted, halted, or prevented from beginning at all.

63. This is only intensified in research that relies on outside participation. Building an accurate, responsive, and representative survey class is an effort that takes both time and money, and programmatic delays in research can impact respondent's willingness to participate in present or future surveys. And in the rare instances where APHA members are participating in clinical research, programmatic delays can become literal life and death matters.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 25th day of April 2025.

Georges C. Benjamin, M.D.

EXHIBIT A

This notice has expired. Check the NIH Guide (https://grants.nih.gov/funding/searchguide/) for active opportunities and notices.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Institute of General Medical Sciences (NIGMS (http://www.nigms.nih.gov))

Funding Opportunity Title

Maximizing Access to Research Careers (T34)

Activity Code

T34 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t34&Search.x=0&Search.y=0&Search_Type=Activity) MARC Undergraduate NRSA Institutional Grants

Announcement Type

Reissue of PAR-19-219 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-219.html) - Maximizing Access to Research Careers (T34)

Related Notices

- **March 28, 2024** - This PAR has been reissued as PAR-24-138 (//grants.nih.gov/grants/guide/pa-files/PAR-24-138.html)
- **March 15, 2023** - Notice of Informational Webinar on the NIGMS U-RISE and MARC Programs (T34). See Notice NOT-GM-23-037 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-23-037.html)
- NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available
- **March 4, 2022** - Clarification of Eligibility for Institutions with Multiple Campuses in PAR-21-147. See Notice NOT-GM-23-013 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-23-013.html)
- NOT-OD-22-190 (/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022
- **March 4, 2022** - Notice of Informational Webinar on the NIGMS U-RISE and MARC Programs. See Notice NOT-GM-22-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-22-031.html).
- **October 28, 2021** - Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 - New Grant Application Instructions Now Available. See Notice NOT-OD-22-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-018.html).
- **September 13, 2021** - Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice NOT-OD-21-181 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-181.html).
- **August 5, 2021** - New NIH "FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice NOT-OD-21-169 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-169.html)
- **August 5, 2021** - Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice NOT-OD-21-170 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-170.html)
- **April 20, 2021** - Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice NOT-OD-21-109 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-109.html)

EXPIRED

- **May 28, 2021** - Notice of Change to the Instructions for Appendices in PAR-21-147. See Notice NOT-GM-21-048 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-048.html).
- **March 19, 2021** - Notice of Informational Webinar on the NIGMS U-RISE and MARC Programs. See Notice NOT-GM-21-034 (/grants/guide/notice-files/NOT-GM-21-034.html).

Funding Opportunity Announcement (FOA) Number

PAR-21-147

Companion Funding Opportunity

Not Applicable

Number of Applications

Only one application per institution is allowed, as defined in Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.859

Funding Opportunity Purpose

The goal of the Maximizing Access to Research Careers (MARC) program is to develop a diverse pool of undergraduates who complete their baccalaureate degree, and transition into and complete biomedical, research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.). This funding opportunity announcement (FOA) provides support to eligible, domestic institutions to develop and implement effective, evidence-informed approaches to biomedical training and mentoring that will keep pace with the rapid evolution of the research enterprise. NIGMS expects that the proposed research training programs will incorporate didactic, research, mentoring, and career development elements to prepare trainees for the completion of research-focused higher degree programs in biomedical fields. This program is limited to applications from training programs at baccalaureate degree-granting research-intensive institutions (i.e., those with an average of NIH Research Project Grant funding greater than or equal to $7.5 million total costs over the last 3 fiscal years).

This Funding Opportunity Announcement (FOA) does not allow appointed trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Key Dates

Posted Date

February 23, 2021

Open Date (Earliest Submission Date)

April 26, 2021

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

May 26, 2021; May 26, 2022; May 26, 2023

All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

October - November 2021, October - November 2022, October - November 2023

Advisory Council Review

January 2022, January 2023, January 2024

Earliest Start Date

June 2022, June 2023, June 2024

Expiration Date

May 27, 2023

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Training (T) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.php?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and

clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (NRSA) (//grants.nih.gov/grants/guide/url_redirect.php?id=41125) website.

Purpose and Background Information

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Each program should provide high-quality research training, mentored research experiences, and additional training opportunities that equip trainees with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design and interpretation of data) and professional (e.g., management, leadership, communication, and teamwork) skills required for careers in the biomedical research workforce.

The National Institutes of Health (NIH) recognizes the need to diversify the scientific workforce by enhancing the participation of individuals from groups identified as underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html) in the biomedical, clinical, behavioral and social sciences (collectively termed "biomedical") research workforce. Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual interests to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of research, enhancing public trust, and increasing the likelihood that health disparities and the needs of underserved populations are addressed in biomedical research.

NIGMS strives to ensure that future generations of researchers will be drawn from the entire pool of talented individuals, bringing different aptitudes, perspectives, interests, and experiences to address complex scientific problems. NIGMS seeks to enhance the diversity of the biomedical research workforce by supporting individuals from a variety of backgrounds at multiple training and career stages in a variety of institutions and educational settings across the country. Accordingly, NIGMS developed separate institutional eligibility tracks for review and funding of its undergraduate and graduate diversity enhancing programs based on NIH research project grant (RPG) (https://grants.nih.gov/grants/glossary.htm#ResearchProjectGrantRPG) funding levels. The two tracks include research-intensive, i.e., those with an average of NIH RPG funding greater than or equal to $7.5 million total costs per year over the past 3 fiscal years, and research-active, i.e., those with an average of RPG funding less than $7.5 million total costs per year over the past 3 fiscal years (RPG data are available through NIH RePORTER (https://report.nih.gov/award/index.cfm)). To prevent the duplication of diversity enhancing NIGMS programs, each institution will be eligible for one diversity enhancing undergraduate program (either Maximizing Access to Research Careers, MARC (https://www.nigms.nih.gov/training/marc/pages/ustarawards.aspx), or Undergraduate Research Training Initiative for Student Enhancement, U-RISE (https://www.nigms.nih.gov/training/RISE/Pages/U-RISE-T34.aspx)) regardless of the activity code (R25 or T34), and one diversity enhancing graduate program (either the Initiative to Maximize Student Development, IMSD (https://www.nigms.nih.gov/training/IMSD/pages/default.aspx), or Graduate Research Training Initiative for Student Enhancement, G-RISE (https://www.nigms.nih.gov/training/RISE/Pages/G-RISE-T32.aspx)) regardless of the activity code (R25 or T32). Institutions with MARC, U-RISE, IMSD or G-RISE are eligible to participate in the Bridges to the Baccalaureate and/or Bridges to the Doctorate programs provided other eligibility requirements are met.

Need for the Program

In spite of recent advances, individuals from certain groups and backgrounds are underrepresented in the biomedical sciences research workforce as described in NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html). The severity of the underrepresentation of these groups increases throughout the training stages. For example in 2017, students from certain racial and ethnic groups, including Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders comprised ~35 percent of the college age population, but earned only ~25 percent of bachelor's degrees and ~16 percent of Ph.D. degrees in science and engineering (National Center for Science and Engineering Statistics (https://ncses.nsf.gov/pubs/nsb20197/demographic-attributes-of-s-e-degree-recipients#s-e-degrees-by-race-and-ethnicity)). Additionally, while the United States has seen a significant increase in the number of Ph.D. degrees in the biomedical sciences earned by scientists from groups underrepresented in the biomedical research workforce, a corresponding increase in the ranks of the faculty in basic science departments at medical schools has not occurred (Gibbs, et al., 2016, eLife 2016, 5:e21393; Valantine, Lund & Gammie, CBE-Life Sciences Education, 2016, 15:fe4).

Several reports (see for example, ACD Working Group on Diversity in the Biomedical Workforce, 2012 (https://acd.od.nih.gov/documents/reports/DiversityBiomedicalResearchWorkforceReport.pdf); PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf); From College to Careers: Fostering Inclusion of Persons with Disabilities in STEM, 2014 (http://www.sciencemag.org/booklets/college-careers); and Increasing College Opportunity for Low Income Students, 2014

(https://obamawhitehouse.archives.gov/sites/default/files/docs/increasing_college_opportunity_for_low-income_students_report.pdf)) recommend supporting programs that strive to recruit, train, and mentor students from underrepresented groups who have an interest in science, technology, engineering and math (STEM) as a means to effectively build a diverse and competitive scientific workforce.

Programmatic Approach

This FOA is intended to enable the community to develop and implement evidence-informed approaches to biomedical research training and mentoring to enhance diversity in the biomedical research workforce. The President's Council of Advisors on Science and Technology (PCAST) report provided evidence that financial concerns and a deficit of peers from similar backgrounds can erode self-confidence and the will to remain in STEM majors (PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf)). NIGMS diversity enhancing institutional training grants offset the cost of appointed trainee stipends, tuition and fees, and training related expenses, including health insurance, in accordance with the approved NIH support levels. Additionally, funded programs are expected to provide activities that will build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members. Programmatic activities include, but are not limited to, providing authentic research experiences, academic enhancements, skills development, and additional mentoring - activities proven to increase persistence in STEM fields (cited in PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf) and Graduate STEM Education for the 21st Century, 2018 (https://www.nap.edu/catalog/25038/graduate-stem-education-for-the-21st-century)). Each program should provide high-quality training that equips individuals with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design, and interpretation of data, conducting research in the safest manner possible) and professional (e.g., management, leadership, communication, and teamwork) skills required for careers in the biomedical research workforce. Funded programs are expected to promote inclusive research environments (i.e., institutional and departmental environments where trainees from all backgrounds feel integrated into and supported by the biomedical research community).

Program Objective

The **Overarching Objective** of the Maximizing Access to Research Careers program is to develop a diverse pool of undergraduates who complete their baccalaureate degree and transition into and complete biomedical, research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.). The long-term goal is to develop a diverse pool of well-trained biomedical scientists, who have the following technical, operational, and professional skills:

- A broad understanding across biomedical disciplines and the skills to independently acquire the knowledge needed to advance their chosen fields;
- Expertise in a biomedical scientific discipline and the skills to think critically and independently, and to identify important biomedical research questions and approaches that push forward the boundaries of their areas of study;
- A strong foundation in scientific reasoning, rigorous research design, experimental methods, quantitative and computational approaches, and data analysis and interpretation;
- The skills to conduct research in the safest manner possible, and a commitment to approaching and conducting biomedical research responsibly, ethically, and with integrity;
- Experience initiating, conducting, interpreting, and presenting rigorous and reproducible biomedical research with increasing self-direction;
- The ability to work effectively in teams with colleagues from a variety of cultural and scientific backgrounds, and to promote inclusive and supportive scientific research environments;
- The skills to teach and communicate scientific research methodologies and findings to a wide variety of audiences (e.g., discipline-specific, across disciplines, and the public); and
- The knowledge, professional skills and experiences required to identify and transition into careers in the biomedical research workforce (i.e., the breadth of careers that sustain biomedical research in areas that are relevant to the NIH mission).

Diversity at all levels from the kinds of science to the regions in which it is conducted to the backgrounds of the people conducting it contributes to excellence in research training environments and strengthens the research enterprise. This FOA is intended to support outstanding research training programs that will enhance diversity at all levels. As part of a larger initiative to enhance diversity, the MARC program will support trainees who are earning a baccalaureate degree at research-intensive institutions and who intend to complete a biomedical research higher degree program (e.g., Ph.D., or M.D./Ph.D.).

Program Considerations

NIGMS intends to fund applications that propose feasible academic and research focused training programs that will enhance diversity in the biomedical workforce. Applicants are expected to identify training objectives (i.e., specific, measurable, and obtainable outcomes the program intends to achieve) and to develop plans to implement evidence-informed training and mentoring activities that are grounded in the literature and from evaluations of existing relevant programs. Program objectives must align with the overarching goal of the MARC diversity enhancing program. Funded programs are expected to provide evidence of accomplishing the training objectives in progress reports and when applying for renewal, to make training and career outcomes publicly available, and are strongly encouraged to disseminate successful training practices to the broader community.

Institutional commitment and support for the proposed training program are important elements of the application. The MARC program may complement and synergize with other ongoing federally-supported predoctoral research training programs at the applicant institution (e.g., in the development of skills needed for careers in the biomedical research workforce); however, the MARC program goals and activities to achieve those goals must be distinct from related programs currently receiving federal support at the same institution. In cases where an institution has multiple NIGMS training grants, it is expected that these programs will seek to create administrative and training efficiencies to reduce costs and improve trainee services and outcomes. The training grant should be well integrated within one or more department(s)/program(s) and should exert a strong, positive influence on the development and execution of the outreach and recruitment of potential trainees, curriculum, training opportunities, and mentoring. Training grant funds may not be used solely as a vehicle to provide stipends for trainees to conduct research.

Training grants are usually awarded for five years. The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels. Trainees are typically provided full-time support for two to three years of undergraduate studies. Use of training grant support in the final three years of undergraduate research training is strongly encouraged to allow for the participation in research, training, mentoring, professional development, and cohort-building activities that will prepare the trainees to successfully transition into a biomedical, research-focused higher degree program (e.g., Ph.D. or M.D./Ph.D.).

This FOA does not allow appointed trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Renewal of grants funded through PAR-19-219 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-219.html)
Resubmission

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials

Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets should reflect the actual needs of the proposed project.

Recipients are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (*NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

NIGMS recognizes the need of trainees to attend scientific meetings and/or training events, and to build professional networks. NIGMS will provide up to $1,000 per trainee per year for scientific meetings or research training experiences that will enhance scientific development, build science identity, create a sense of belonging in the scientific community, and build professional networks. Plans for trainee travel should be well justified. For MARC-supported institutions outside the continental United States, $1,250 for travel per trainee per year will be provided.

Trainees are required to spend at least one summer in a research training experience. Preferred sites are research-intensive graduate institutions such as those with NIH T32 training programs. Funds for the summer research experience will be provided as follows: $3,000 per MARC trainee, to be used in accordance with the institutional policies as a per diem for a period of up to ten weeks; and an additional $500 for travel to and from the host research training.

NIGMS provides funds for the summer research training experience for up to 50% of the awarded number of MARC trainees at the time a competing award is made. For additional budget guidance on the MARC summer research requirement, see T34 Summer Research Experience Policy (https://www.nigms.nih.gov/training/T34/Pages/sre.aspx). Additional funds will not be provided for students continuing the research training at the host institution.

Plans for trainee travel should be well justified. Foreign travel is not allowed.

Training Related Expenses

NIGMS will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, equipment, research supplies, and faculty/staff travel directly related to the research training program.

The total amount of Training Related Expenses (TRE) that may be requested is limited to a maximum of $8,000/trainee/year. The maximum cap for the TRE portion of a proposed MARC budget is $250,000/year.

Allowable costs include those associated with the following:

- Skills development training activities (e.g., focusing on quantitative and computational skills, problem-solving, critical thinking, scientific writing, effective communication, and project management);
- Seminar speakers, who will serve as role models to the trainees;

- Training or mentoring interventions designed to increase persistence in research careers (e.g., those designed to increase science identity, self-efficacy and a sense of belonging in the scientific community);
- Salary support for the PD/PI or a combination of multiple PD(s)/PI(s)/co-Investigators. Typically, salary support does not exceed 1.8 person months (i.e., 15% effort on a 12-month basis in total) depending on the size and scope of the program;
- Salary support for administrative personnel; typically, the total combined salary support for program administrator/program coordinator and/or program assistant/clerical support does not exceed 3.0 person months (i.e., 25% effort on a 12-month basis) depending on the size and scope of the program.
- Limited program evaluation costs (typically up to $3,000 for the 5-year training grant period) and other program-related expenses may be included within the budget for training-related expenses.

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of $25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIH grants policies as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Predominantly Black Institutions (PBI)
- Tribally Controlled Colleges and Universities (TCCUs)
- American Indian/Alaska Native Serving, Non-Tribal Institutions (AI/AN)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

For diversity enhancing programs, NIGMS recognizes separate institutional eligibility tracks: research-intensive, i.e., those with an average of NIH research project grant (RPG) (https://grants.nih.gov/grants/glossary.htm#ResearchProjectGrantRPG) funding greater than or equal to $7.5 million total costs per year over the past 3 fiscal years, and research-active, i.e., those with an average of RPG funding less than $7.5 million total costs per year over the past 3 fiscal years (RPG data are available through NIH

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Institutional eligibility for this FOA is limited to baccalaureate degree-granting research-intensive institutions as defined above. Research-active institutions are not eligible to apply for or receive MARC grants. To prevent the duplication of NIGMS diversity enhancing programs, each institution is eligible for one undergraduate program (either MARC (https://www.nigms.nih.gov/training/marc/pages/ustarawards.aspx) or U-RISE (https://www.nigms.nih.gov/training/RISE/Pages/U-RISE-T34.aspx)) regardless of the activity code (R25 or T34), and one graduate program (either IMSD (https://www.nigms.nih.gov/training/IMSD/pages/default.aspx) or G-RISE (https://www.nigms.nih.gov/training/RISE/Pages/G-RISE-T32.aspx)) regardless of the activity code (R25 or T32). Institutions with NIGMS MARC, U-RISE, IMSD, or G-RISE funding are eligible for the Bridges to the Baccalaureate and/or Bridges to the Doctorate programs provided the other eligibility criteria are met. Applicants are encouraged to consult NIGMS staff to discuss eligibility prior to submission.

An institution funded through the U-RISE or MARC program that changes category due to changes in research project grant funding during the grant cycle should apply to the appropriate program based on their eligibility at the time of renewal. Programs that change category will report on the programs outcomes of the prior funding period(s), up to 15 years, using the appropriate tables.

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program should be detailed in the *Institutional Support Letter* in the **Letters of Support** attachment. Additionally, a signed letter is required from the Provost or similar official with institution-wide responsibility verifying the eligibility of the applicant institution at the time of application submission according to the eligibility criteria indicated above. See the application instructions for the required Letters of Support instructions in Section IV.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the

organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy (//grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

As described in the instructions for the Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) in Section IV.2 below, NIGMS encourages multiple PDs/PIs, particularly when each brings a unique perspective and skill set that will enhance training. At least one of the training PD(s)/PI(s) should be an established investigator in the biomedical sciences and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. Additional PDs/PIs, including individuals with experience in the science of education, relevant social science disciplines, program evaluation, mentoring, and university administration may be included to achieve the training goals. Any of the PDs/PIs may serve as the contact PD/PI. The contact PD/PI is expected to have a full-time appointment at the applicant institution unless extremely well-justified. If the full-time status of the contact PD/PI changes after the award, the institution must obtain prior program approval to appoint a new PD/PI or request a deviation from the full-time rule. The PD(s)/PI(s) will be responsible for the selection and appointment of trainees to the approved research training program, and for the overall direction, management, administration, and evaluation of the program. The PD(s)/PI(s) will be expected to monitor and assess the program and submit all documents and reports as required. The PD(s)/PI(s) have responsibility for the day-to-day administration of the program and are responsible for appointing members of the Advisory Committee (when applicable) and using their recommendations to determine the appropriate allotment of funds.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement*. (//grants.nih.gov/grants/guide/url_redirect.php?id=11126)

3. Additional Information on Eligibility

Number of Applications

NIGMS will accept only one application per institution, typically defined by a unique identifier, such as DUNS (https://fedgov.dnb.com/webform/) and an NIH Institution Profile File (IPF) (https://public.era.nih.gov/commons/public/quickqueries/ipfNumberByOrgName.era) number.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Preceptors/Mentors (Participating Faculty)

The selected faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support. When building a training team, programs should include faculty who are committed to training, mentoring, and providing supportive and inclusive research environments. Programs are encouraged to build a diverse team of preceptors/mentors that includes, for example, faculty from underrepresented groups (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) and faculty at different career stages (i.e., early-career as well as established faculty).

Trainees

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The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

Trainees should be research-oriented individuals enrolled in a major leading to a baccalaureate degree in a STEM discipline that will prepare the trainee for a biomedical, research-focused higher degree program (e.g., Ph.D. or M.D./Ph.D.). All trainees are required to pursue their research training full time as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments for 2-3 years, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the NIH awarding unit.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Training (T) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.php?id=12000) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.php?id=61134) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

Follow all instructions provided in the SF424 (R&R) Application Guide.

SF424(R&R) Project/Performance Site Locations

Follow all instructions provided in the SF424 (R&R) Application.

SF424 (R&R) Other Project Information

Follow all instructions provided in the SF424 (R&R) Application, with the following modifications:

Are Human Subjects Involved: Check "No" unless the training program itself requires the trainees to take a workshop or course that will involve human subjects.

Are Vertebrate Animals Used: Check "No" unless the training program itself requires the trainees to take a workshop or course that will involve vertebrate animals.

Project Summary/Abstract: Provide an overview of the entire program. Include the mission, objectives, rationale and design of the research training program. Highlight key activities in the training plan that promote skills development and the successful transition into and completion of biomedical, research-focused higher degree programs. Indicate the intended trainee outcomes.

Other Attachments.

Advisory Committee (1-page maximum). An Advisory Committee is not a required component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training program. The roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will assess the overall effectiveness of the program. To avoid conflicts in the review process, only pre-existing Advisory Committee members should be named in the application. Potential Advisory Committee members should not be identified or contacted prior to receiving an award. Please name the file Advisory_Committee.pdf .

Recruitment Plan to Enhance Diversity (3-page maximum). The applicant must provide a *Recruitment Plan to Enhance Diversity*. The application should include outreach strategies and activities designed to recruit potential training program candidates who are from diverse backgrounds, including students from underrepresented racial and ethnic groups, individuals with disabilities, and students from disadvantaged backgrounds (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)). Applicants are encouraged to consult the NIGMS webpage for strategies to enhance diversity in training programs (https://www.nigms.nih.gov/training/diversity/pages/approaches.aspx) when designing their plans. Describe the specific efforts to be undertaken by the training program and how these might coordinate with trainee recruitment efforts of the institution. Centralized institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups. Participating faculty are expected to be actively involved in recruitment efforts. Please name the file Recruitment_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Trainee Retention Plan (3-page maximum). The applicant must provide a *Trainee Retention Plan*. The *Trainee Retention Plan* must describe efforts to sustain the scientific interests as well as monitor the academic and research progress of trainees from all backgrounds within a program (i.e., retention). Applicants are encouraged to consult the NIH's extramural diversity website to identify promising retention practices (https://extramural-diversity.nih.gov/building-participation/recruitment-retention) and to use evidence-informed practices for retention with the recognition that the variety of trainee backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with trainee retention efforts of the institution(s). Centralized institutional efforts alone will not satisfy the requirement to implement robust and successful mechanisms to retain all trainees (e.g., participating faculty are expected to be actively involved in trainee retention efforts). Please name the file Retention_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Outcomes Data Collection and Storage Plan (2-page maximum). The applicant must provide an *Outcomes Data Collection and Storage Plan* to track the outcomes for all supported trainees for a minimum of 15 years beyond the trainee's participation in the program. Programs are encouraged to make the aggregate outcome data available on the institution's website. If the applicant intends to make the data available, describe how the aggregate data will be de-identified before public posting. The applicant must include a strategy to ensure the secure storage and preservation of program data and outcomes. Describe how the data will be centralized, safeguarded, and retrievable during leadership changes. Please name the file Data_Collection_Storage_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Dissemination Plan (1-page maximum). The application must provide a specific *Dissemination Plan* to publish or present nationally any findings or materials developed under the auspices of the program. Examples of dissemination may include data or materials from successful training or mentoring interventions via web postings, presentations at scientific meetings, and/or workshops. Please name the file Dissemination_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

The filename provided for each Other Attachment will be the name used for the bookmark in the electronic application in eRA Commons.

SF424(R&R) Senior/Key Person Profile Expanded

Follow all instructions provided in the SF424 (R&R) Application with the following modifications.

Biographical sketch. The personal statement should describe a commitment to scientific rigor, research training, mentoring, as well as to promoting inclusive, safe, and supportive scientific environments.

PHS 398 Cover Page Supplement

Follow all instructions provided in the SF424 (R&R) Application.

PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the SF424 (R&R) Application Guide.

Training Budget

Follow all instructions provided in the SF424 (R&R) Application Guide.

PHS 398 Research Training Program Plan

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program

- Faculty, Trainees, and Training Record
- Other Training Program Sections
- Appendix - Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the FOA specifically instructs applicants to do so.

Follow all instructions provided in the SF424 (R&R) Application Guide with the following modifications:

Attention must be given to the required Training Data Tables (//grants.nih.gov/grants/guide/url_redirect.php?id=61169) for undergraduate programs (Tables 2, 3, 4, 5C, and 8D). In the Program Plan, applicants should also summarize key data from the tables that highlight the characteristics of the applicant pool, program faculty, institutional support, student outcomes, and other factors that contribute to the overall training environment of the program.

Training Program

Follow all training instructions provided in the SF424 (R&R) application guide except where instructed to do otherwise below.

Program Plan

The "Program Plan" attachment is required and must adhere to the NIH Table of Page Limits (https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm#train), as well as the organization and instructions provided below.

Do not follow the organization and instructions provided in the SF424 (R&R) application guide for the Program Plan attachment; instead applicants must use the instructions below. Start each section with the appropriate heading.

Rationale, Mission, and Objectives

The application should describe how the MARC program will develop a diverse pool of well-trained scientists who have the technical, operational, and professional skills required to conduct research in a safe, ethically responsible and rigorous manner, and to enter the next phase of the career pathway as delineated in the Program Objective. The application should describe how the program will enhance the training environment and not simply provide financial support to the trainees. Specifically, applicants should describe the following:

- The justification for the proposed diversity enhancing research training program. The application should describe the current institutional efforts to promote diversity and to create inclusive research training environments and how the MARC program will enhance, but not duplicate these efforts. The rationale for the program should expand upon the "Training Outcome" data requested below that provides institutional baseline data on previous student outcomes comparing success rates for groups that are well-represented and underrepresented in the biomedical research workforce (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html));
- Current research training environment and student demographics. The application should describe the research training environment including, but not limited to, the relevant background, an overview of the current research training activities of the participating department(s) or unit(s), and areas for improvement in the current research training practices. The application must demonstrate the presence of a sufficient number of potential trainees from diverse backgrounds, for example, those from underrepresented groups (applicants are encouraged to use the Suggested Table Formats A.1, A.2, and A.3 (https://www.nigms.nih.gov/training/MARC/pages/MARCtables.aspx) found on the NIGMS webpage to present the data; any Suggested, or other, Tables must be included in the Training Program section and will count towards the 25-page limit), and of faculty mentors/participating faculty in the appropriate biomedical fields (Tables 2 and 4 (https://grants.nih.gov/grants/forms/data-tables.htm)). The application should also demonstrate the existence of sufficient resources to achieve the training objectives (Table 3 (https://grants.nih.gov/grants/forms/data-tables.htm)); and
- The training mission (i.e., broad statement of purpose of the program), and objectives (i.e., specific measurable outcomes the program intends to achieve). The baseline data, the trainee pool, and the institutional context should inform the objectives and the design of the proposed training program. The program-specific mission and objectives should align with the Overarching Objective of this funding announcement. Objectives should include, but not be limited to, baccalaureate degree completion rates, appropriate time-to-degree, and the rate of transitioning into and completion of research-focused higher degree programs.

Curriculum and Overall Training Plan

The application should describe the following:

- How the courses, structured activities, and research experiences will accomplish the specific training mission and objectives. Explain how these training activities are designed to develop the technical, operational, and professional skills of trainees. The application must include the "Required Training Activities" appendix to provide material to assess the required training elements and may use the "Elective Activities" appendix to provide up to four additional activities;
- Proposed changes to current research training practices to keep pace with the rapidly evolving biomedical research enterprise (e.g., curricular reforms, incorporation of additional quantitative and computational skills development, etc.);
- The mechanisms to ensure that trainees participate in authentic research experiences throughout the training period. Applications that propose classroom-centered research training activities should describe the learning objectives, course attributes, participating faculty, training frequency, and expected trainee outcomes. If trainee research experiences are proposed to include other institutions, describe how the PD(s)/PI(s) will interact with the research mentors to promote trainee success;
- The plans to ensure that MARC trainees complete at least one summer research training experience at a research-intensive institution (either at an external site or at the home institution). Preferable sites are graduate institutions that offer NIH T32 predoctoral programs. To assist with this interaction, NIGMS maintains a list of NIGMS-funded T32 programs (http://www.nigms.nih.gov/training/pages/InstGrantLists.aspx). Other NIH Institutes and Centers also support the T32 predoctoral training program in various research areas. For a query search to identify such programs, visit the NIH Research Portfolio Online Reporting Tools (RePORT (http://report.nih.gov/index.aspx)) website;
- The mechanism for ensuring that the trainees are learning the highest standards of practice in biomedical research (e.g., record keeping and safety);
- How the Participating Faculty will teach laboratory safety throughout the didactic and mentored portions of the program;
- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, inclusion, and professional development;
- The activities that will build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members;
- Representative examples of training programs for individual trainees. Examples may include degree requirements, didactic courses, laboratory experiences, and other training activities, such as seminars, journal clubs, etc. Describe how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated. Discuss the anticipated time required to complete the training program up to degree attainment;
- The trainees academic and research background needed to pursue the proposed training and plans to accommodate differences in preparation among trainees.
- How the training activities will be available to other trainees in the program(s), department(s) or institution(s) from which the supported trainees are drawn;
- For multi-disciplinary and/or multi-departmental programs, indicate how the individual disciplinary and/or departmental components of the program are integrated and coordinated, and how they will relate to an individual trainee's experience; and
- The ways, when applicable, that the training plan is distinct from, but will share resources and synergize with, other NIGMS-funded predoctoral training programs at the same institution (i.e., NIGMS predoctoral training programs listed in Table 3 (https://grants.nih.gov/grants/forms/data-tables.htm)). See the "Program Considerations" section above.

Career Development

The application should describe the following:

- How the pool of potential applicants and trainees will be provided with information about the career outcomes of graduates of the program (e.g., on publicly accessible websites) and about the overall biomedical research workforce employment landscape;
- How trainees will be provided with support as well as adequate, appropriate, and timely information regarding the steps required to transition into the next phase of the biomedical research workforce pathway (e.g., when applying to research-focused graduate programs, or funding opportunities);
- How the trainees will be sponsored or mentored by individuals who will enhance their career opportunities (e.g., contacts at national meetings and institutions with NIH-funded T32 training programs, as well as members of scientific societies, and the research community);

Program Oversight, Participating Faculty Selection, and Mentor Training

The application should include the planned strategy and administrative structure to oversee and monitor the program, and to ensure appropriate and timely trainee progress for the duration of the trainees' undergraduate careers (the application may

include the "Evaluation and Assessment Instruments" Appendix to provide blank rubrics or forms). The application should describe how the participating faculty are trained to ensure the use of evidence-informed teaching, training and mentoring practices that promote the development of trainees from all backgrounds, e.g., trainees from underrepresented backgrounds in the biomedical sciences (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)). Applicants should describe the following:

- How the program will ensure that participating faculty employ the highest standards of scientific rigor and impart those standards to their trainees;
- How the program will ensure that participating faculty reinforce and augment the curricular material on responsible conduct of research, and methods for enhancing reproducibility;
- The mechanism for matching trainees with the appropriate participating faculty mentors;
- How the program will ensure that participating faculty engage in activities that promote trainee career development (including but not limited to the utilization of Individual Development Plans) and fulfill the need of the trainees to obtain their degrees in a timely fashion with the skills, credentials, and experiences to transition into the next phase of the biomedical research career pathway that are consistent with the trainees interests and values;
- A mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty displaying unacceptable mentorship qualities from the training program (applicants may use the Appendix labeled Conflict Resolution Protocols to provide details of the plan); and
- If a program coordinator or administrator position is planned to enhance oversight, a description of the person's administrative capabilities that are essential to coordinate the program must be included in the application.

Institutional and Departmental Commitment to the Program

A letter providing assurances of the institutional commitment to the program must be included in the *Institutional Support Letter* in the **"Letters of Support"** section of the application. In addition, applicants may use this section of the Training Program to expand upon the **Facilities & Other Resources** section and the **Letters of Suppor**t section, as necessary, to provide additional information regarding the institutional and departmental commitment to the program. Do not repeat information contained elsewhere in the application.

This section or the *Institutional Support Letter* should address how research training at the undergraduate level is supported. Additional examples of institutional commitment specific to undergraduate biomedical research training may include, but are not limited to:

- Support of an Office of Undergraduate Research;
- Stipend and tuition remission for research-oriented undergraduates;
- Undergraduate biomedical research counting towards course credit hours and/or degree requirements;
- Funds and protected time for faculty to develop course-based undergraduate research experiences that will fulfill degree requirements;
- Funds to sustain research-oriented courses;
- Faculty teaching models that support integrated/interdisciplinary STEM curricula and courses;
- Support of research training administrators and coordinators;
- Supervised student access to research facilities during non-standard work hours; and
- Personnel dedicated to undergraduate student success and oversight (e.g., tutoring and academic support services, infrastructure to identify students in need).

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) will promote the success of the trainees and training program. NIGMS encourages multiple PDs/PIs, particularly when each brings a unique perspective and skill set that will enhance training as described in the Eligible Individuals section. The application should expand on the information in the biosketch(es) to address how the PD/PI or PD/PI team has:

- The expertise, as well as the administrative and training experience, to provide strong leadership, direction, management, and administration of the proposed research training program;
- The time to commit sufficient effort to ensure the program's success given other professional obligations (the application should indicate the PD(s)/PI(s) s percent effort in the proposed program);
- At least one member of the team who has the scientific expertise in the biomedical sciences and who has a record of using rigorous and transparent methods in experimental design, data collection, analysis, and reporting;

- A demonstrated commitment to training the next generation of the biomedical research workforce, leading recruitment efforts to enhance diversity, and fostering inclusive research environments. As with all participating faculty, the PD(s)/PI(s) should have received training on how to effectively mentor trainees from all backgrounds, e.g., trainees from groups underrepresented in the biomedical sciences (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)); and
- A clearly delineated administrative structure and leadership succession plan for critical positions (e.g., PD(s)/PI(s)).

Preceptors/Mentors (Participating Faculty)

The application should describe how the participating faculty will promote the success of the trainees and training program, as well as conducting responsible and rigorous research. Describe how the program has or will assemble a diverse team of participating faculty (e.g., individuals from underrepresented backgrounds (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-053.html)), women, and faculty at different career stages) to provide potential role models within the training program and to enhance the excellence of the training environment. The application should summarize and expand on the material presented in the Training Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and biosketches and address how the participating faculty:

- Have sufficient time to commit to training given their other professional obligations;
- Receive training in effective, evidence-informed teaching and mentoring practices;
- Promote the use of highest standards of practice to ensure the safety of all individuals in the research environment;
- Cooperate, interact, and collaborate (which can include joint sponsorship of trainee research);
- Promote the development of trainee skills in approaches to rigorous experimental design, methods of data collection, data analysis and interpretation, and reporting;
- Provide opportunities for trainees to initiate, conduct, interpret, and present rigorous, reproducible and responsible biomedical research with increasing self-direction;
- Demonstrate a commitment to effective mentoring, and to promoting inclusive, safe and supportive scientific and training environments; and
- Are evaluated as teachers and mentors.

Trainee Positions, Appointment Process, Retention and Support

Through the narrative and summaries of the information presented in the required Training Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and the required attachments the following areas relevant to trainees should be addressed.

- Provide a strong justification for the number of requested trainee positions in the context of the training grant eligible pool described in the rationale section of the application and other training programs at the institution. Potential trainees should be research-oriented individuals enrolled in a major leading to a baccalaureate degree in a STEM discipline that will prepare the individual for a biomedical, research-focused higher degree program (e.g., Ph.D. or M.D./Ph.D.). *For Renewal Applications* - Describe the characteristics of the previously awarded trainees as part of the justification for the requested positions.;
- Explain the proposed training grant support structure, i.e., how many individuals (e.g., 4 per year), at what stage (e.g., third- and fourth-year students), and for how long (e.g., for 2 years); and
- Describe the review process to identify research-oriented candidates for the program. Programs are encouraged to develop a process that considers metrics beyond grade point average, and standardized test scores and that will identify promising candidates who are committed to contributing to the biomedical research enterprise and who, with training and support, will be competitive for research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.).
- Applicants may use this section to expand upon the Trainee Retention Plan (provided in the "Other Attachments") and to provide evidence of the program's commitment to ensuring the well-being and success of all trainees throughout their training.

Training Outcomes

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for training grant eligible students for the proposed program). The application should provide information below about recent outcomes through narrative descriptions and a summary of the data presented in the required training tables (https://grants.nih.gov/grants/forms/data-tables.htm). Although the training tables for new applications only allow for five years of recent outcomes, the application may describe up to 15 years of outcomes in the narrative. Applicants are encouraged to provide outcome data using the Suggested Table Formats B.1, B.2, or B.3

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(https://www.nigms.nih.gov/training/MARC/pages/MARCtables.aspx) found on the NIGMS webpage. The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications, or other measures of scientific accomplishment appropriate to the field such as presentations at national meetings and receiving fellowships);
- The rate of baccalaureate degree attainment and time-to-degree for recent graduates. The application must include outcome data regarding the number of former individuals in the program who graduated with a baccalaureate degree in a STEM field (obtained goal), remained in the program (still in training), or did not obtain a baccalaureate degree (attrition). The application should include institutional comparator groups (e.g., students with similar demographics and aptitude metrics who were not in the program) and the graduation rates for all students in the STEM fields represented; and
- The success of former students transitioning to the next phase in the biomedical research workforce pathway (e.g., matriculation to a research-focused higher degree program). Applicants must complete Training Table 8D (https://grants.nih.gov/grants/forms/data-tables.htm), and are encouraged to use the Suggested Table Formats B.1, B.2, or B.3 (https://www.nigms.nih.gov/training/MARC/pages/MARCtables.aspx). Any Suggested, or other, Tables must be included in the Training Program section and will count towards the 25-page limit.

Program Evaluation and Dissemination

NIGMS funded training programs must conduct ongoing evaluations to monitor the success of the training and mentoring activities. The application should describe:

- The evaluation or assessment process to determine whether the overall program is effective in meeting its training mission and objectives, and whether the scientific research climate is inclusive, safe, and supportive of trainee development (the application may include the "Evaluation and Assessment Instruments" Appendix to provide blank survey instruments, rubrics, or forms);
- Plans for being responsive to outcomes analyses, critiques, surveys and evaluations;
- Past activities to track and post the career outcomes of trainees (applicants should expand upon, but not duplicate the information in the Outcomes Data Collection and Storage Plan); and
- Past activities designed to share the outcomes of the training or mentoring interventions with the broader community (applicants should expand upon, but not duplicate the information in the Dissemination Plan).

Plan for Instruction in the Responsible Conduct of Research

Applicants are required to comply with the instructions for Plan for Instruction in the Responsible Conduct of Research as provided in the SF424 (R&R) Application Guide, along with the following additional instructions:

Describe how the Responsible Conduct of Research (RCR) components are well integrated into the overall curriculum, i.e., how they are taught at multiple stages of trainee development and in a variety of formats and contexts. Explain how the teaching of RCR synergizes with elements of the curriculum designed to enhance trainees abilities to conduct rigorous and reproducible research. Describe how all participating faculty will reiterate and augment key elements of responsible conduct when trainees are performing mentored research in their laboratories.

Plan for Instruction in Methods for Enhancing Reproducibility

Applicants are required to provide a Plan for Instruction in Methods for Enhancing Reproducibility

as provided in the SF424 (R&R) Application Guide.

Applicants are encouraged to consult the NIGMS clearinghouse for training modules to enhance data reproducibility (https://www.nigms.nih.gov/training/pages/clearinghouse-for-training-modules-to-enhance-data-reproducibility.aspx) and other resources when developing the plans.

Progress Report (only for Renewal applications)

For applications describing programs that were previously funded under PAR-19-219 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-219.html) follow the instructions provided in the SF424 (R&R) Application Guide with the following exceptions:

For the "Program Overview" section, follow the page limit indicated in the SF424 (R&R) application guide, but follow the instructions below instead:

- Indicate the period covered since the last competitive review.
- Include information to demonstrate that the program successfully trained a diverse pool of individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce.
- Describe successes and challenges with regards to implementing the programmatic elements described in the previous application, including but not limited to the following areas:
    - Incorporating evidence-informed training and mentoring practices into the program.
    - Teaching of rigor and transparency, and the responsible and safe conduct of research throughout the training experience.
    - The challenges and successes for enhancing diversity and inclusion.
    - Overseeing all aspects of the program (e.g., of the mentor/mentee matches, the participating faculty, and trainee progress).
    - Preparing trainees for a broad range of careers in the biomedical research workforce (including but not limited to the use of Individual Development Plans, IDPs).
- Provide justifications for failing to implement previously proposed programmatic elements.
- Provide evidence that the specific and measurable objectives described in the previous application were achieved and if not, provide a justification for failing to achieve the objectives.
- Describe how the funds provided under "Training Related Expenses" were used to benefit the program.
- Provide the methods and results of the evaluations of the program activities. Indicate whether the training activities were effective in contributing to the program objectives.
- Provide evidence that the scientific research climate is inclusive, safe, and supportive of trainee development.
- Expand upon the "Training Outcomes" to highlight successes and areas for improvement.
- Describe how the program responded to outcomes analyses, critiques, surveys and evaluations. Describe the barriers to success and indicate changes to the program designed to address these barriers.
- Describe how the program makes training and career outcomes publicly available.
- Indicate whether the PD(s)/PI(s) disseminated nationally any findings or materials developed under the auspices of the program to the broader training community.
- Indicate the broader impact of the program (e.g., on the curriculum, training environment, or institutional practices).
- Highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program.

Faculty, Trainees, and Training Record

Participating Faculty Biosketches

Participating faculty should provide a personal statement that describes the appropriateness of their research background for the proposed training program, and their commitment to the following:

- Training, mentoring, and promoting inclusive, safe and supportive research environments;
- Maintaining a record of, and providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results;
- Promoting the use of highest standards of practice to ensure the safety of all individuals in the research environment;
- Supporting trainees participating in activities required to identify and transition into careers in the biomedical research workforce that are consistent with the trainees skills, interests, and values; and
- Fulfilling the need of the trainees to complete their degrees in a timely fashion with the skills, credentials, and experiences to transition into research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.).

Letters of Support

Institutional Support Letter (10-page maximum). The application must include a signed letter on institutional letterhead from a President, Provost, Dean, or similar key institutional leader that describes the activities and resources provided by the institution that are designed to ensure the success of the planned training program and its trainees. If this letter is not included, the application will be considered incomplete and will not be reviewed. The institutional commitment to the following areas should be described (as applicable):

- Developing and promoting a culture in which the highest standards of safety, scientific rigor, reproducibility, and responsible conduct are advanced;

- Ensuring sufficient start-up funding to permit early stage faculty to participate in training, and bridge funding to ensure that training may continue if a mentor experiences a hiatus in funds;
- Supporting core facilities and technology resources, and describing how they can be used to enhance training;
- Providing adequate staff, facilities, and educational resources to the planned program;
- Supporting the PDs/PIs and other key staff associated with the planned training program;
- Fostering and rewarding excellence in training (e.g., through institutional polices such as tenure and promotion);
- Supporting the remediation or removal of Participating Faculty from the program who are poorly performing mentors;
- Promoting diversity and inclusion at all levels of the research training environment (trainees, staff, faculty, and leadership);
- Ensuring a positive, supportive and inclusive research and training environment for individuals from all backgrounds;
- Ensuring the research facilities and laboratory practices promote the safety of trainees;
- Guaranteeing the research facilities are accessible to trainees with disabilities;
- Ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (e.g., requesting a change of PD/PI status; see NOT-OD-19-029 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-029.html));
- Providing trainees access to student support services, such as healthcare, counseling services, and housing;
- Providing resources and expertise for evaluating the training outcomes of the program; and
- For institutions that have multiple NIGMS-funded predoctoral training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones.

Institutional Eligibility Letter. (1-page maximum). The Authorized Organization Representative or Business Official or similar official with institution-wide responsibility must certify that all the components of the institution under the applicant DUNS or IPF number together have an average of RPG funding greater than or equal to $7.5 million total costs (both direct and F&A/indirect costs) per year over the past 3 fiscal years, as described in Section III, "Eligible Organization". If this letter is not included, the application will be considered incomplete and will not be reviewed.

Other Letters of Support. Additional letters of support (e.g., from partner institutions or organizations) are permitted; however, these letters may not contain any information required in the Institutional Support Letter.

Combine all Letters of Support into a single PDF file.

Data Tables: The application must include the required Training Data Tables (https://grants.nih.gov/grants/guide/url_redirect.php?id=61169). Applications that do not contain the required tables, or that submit any additional tables in this attachment, will be considered noncompliant and will not be reviewed.

Appendix

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to theSF424 (R&R) Application Guide instructions.

The Appendix is meant to provide additional details to the following topics but is not meant to substitute for clear descriptions in the body of the application. Do not include items other than the required and allowable materials described below, as doing so will result in administrative withdrawal of the application prior to review. Name the file according to the headings below. A summary sheet listing all the items included in the Appendix may be included in the first Appendix attachment.

The following are required Appendix materials:

- Required Training Activities. To adequately assess the content of the didactic portion of the training program, the application must include syllabi/outlines of all required training activities (e.g., syllabi for courses, mentor training materials, professional development workshops, career exploration opportunities, skills development activities).
- Responsible Conduct of Research Syllabi. In addition to the Plan for Instruction in the Responsible Conduct of Research, the application must provide syllabi/outlines of materials relating to Responsible Conduct of Research and descriptions of when in the trainees career paths the material is taught.

The following are allowable Appendix materials:

- Elective Activities. The application may include summary content from up to four additional elective courses and/or training activities (e.g., syllabi or summaries for courses, mentor training materials, outlines of professional development workshops, career exploration opportunities, or skills development activities).
- Evaluation and Assessment Instruments. The application may include blank surveys, rubrics, and/or forms used to (a) document and monitor trainee progress and (b) determine whether the training and research environment is effective, inclusive, safe, and supportive.
- Conflict Resolution Protocols (3-page maximum). The application may include detailed protocols for addressing problems with trainee and faculty matches, removal of faculty from the training program with unacceptable training/mentoring skills and for conflict resolutions for multi PD(s)/PI(s) and mentor/mentee relationships.

Applications that do not include the required appendices or that exceed the number of allowed appendices or the page limitation of any of the allowed materials will be considered noncompliant and will not be reviewed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.php?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120). The National Research Service Award (NRSA) policies (//grants.nih.gov/grants/guide/url_redirect.php?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and NIGMS. Applications that are incomplete or non-compliant will not be reviewed.

Applicants Requesting $500,000 or more for direct costs (less consortium F&A) in any year

Applicants requesting $500,000 or more in direct costs in any year **are not required** to contact a Scientific/ Research Contact prior to submitting an application. The Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide **is not** applicable to this FOA.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.php?id=82299).

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will produce a diverse pool of well-trained scientists who complete their baccalaureate degree and transition into and complete biomedical, research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.). Will the program provide trainees with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design, and interpretation of data), and professional (e.g., management, leadership, communication, and teamwork) skills necessary to conduct rigorous and reproducible research, and transition into research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.), in consideration of the following review criteria and additional review criteria (as applicable for the program proposed)?

Specifically, do the courses, structured training activities, mentoring, and research experiences equip the trainees with:

- A broad understanding across biomedical disciplines;
- Expertise in a basic biomedical scientific discipline and the skills to independently acquire the knowledge needed to advance their chosen fields;

- The ability to think critically and independently, and to identify important biomedical research questions and approaches that push forward the boundaries of their areas of study;
- A strong foundation in scientific reasoning, rigorous research design, experimental methods, quantitative and computational approaches, and data analysis and interpretation;
- The skills to conduct research in the safest manner possible, and a commitment to approaching biomedical research responsibly, ethically, and with integrity;
- Experience initiating, conducting, interpreting, and presenting rigorous and reproducible biomedical research with increasing self-direction;
- The ability to work effectively in teams with colleagues from a variety of cultural and scientific backgrounds, and to promote inclusive and supportive scientific research environments;
- The skills to teach and communicate scientific research methodologies and findings to a wide variety of audiences (e.g., discipline-specific, across disciplines, and the public); and
- The knowledge, professional skills and experiences required to identify and transition into careers in the biomedical research workforce (i.e., the breadth of careers that sustain biomedical research in areas that are relevant to the NIH mission)?

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the training program, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Training Program and Environment

Rationale, Mission, and Objectives

- Does the application provide a compelling rationale for the proposed research training program?
- Does the proposed program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines, program faculty with the appropriate scientific expertise, and resources to achieve the training objectives?
- Are the mission and objectives for the training program specific and measurable and in alignment with the goal of the program?

Curriculum and Overall Training Plan

- Will the courses, structured training activities, mentoring, and research experiences achieve the stated mission and objectives of the proposed training program?
- Does the application propose changes in the program's research training and mentoring practices to effectively address the rapidly evolving biomedical research enterprise and current understanding of evidence-informed training and mentoring approaches?
- Will the trainees participate in authentic research experiences and complete at least one summer research training experience at a research-intensive institution?
- Is the mechanism for ensuring that the trainees are learning the highest standards of practice in biomedical research (e.g., record keeping and safety) robust?
- Will the Participating Faculty teach laboratory safety throughout the didactic and mentored portions of the program?
- Does the training program plan provide a compelling explanation of how the courses, structured training activities, mentoring, and research experiences employ modern, evidence-informed approaches that are likely to enhance the success of the trainees?
- Are the activities likely to build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members?
- Do the required and elective training elements (e.g., syllabi, course descriptions) provide compelling evidence that the trainees will gain the requisite skills for the discipline in a timely fashion and that there are mechanisms to ensure that the trainees will be guided, monitored, and evaluated?
- Are there plans to accommodate differences in preparation among trainees?
- Is it clear how the proposed program will enhance the research training environment and not simply provide financial assistance for the trainees?
- Is it clear how the training activities will be available to other students in the program(s), department(s), or institution(s) from which the trainees are drawn?

- For multi-disciplinary and/or multi-departmental programs, is it clear how the individual disciplinary and/or departmental components of the program are integrated and coordinated, and how each will relate to an individual trainee's experience?
- If applicable, is the proposed program distinct from, but planning to share resources and synergize with other NIGMS-funded predoctoral training programs at the institution?

Career Development

- Is there a mechanism to ensure the pool of potential applicants and trainees will be provided with information about the outcomes of former trainees of the program (e.g., on publicly accessible websites) and about the overall biomedical research workforce employment landscape?
- Will the trainees be provided with support as well as adequate, appropriate, and timely information regarding the steps required to transition into the next phase of the biomedical research workforce pathway (e.g., when applying to research-focused graduate programs, or funding opportunities)?
- Will the trainees be introduced to mentors and sponsors who will enhance their career opportunities (e.g., contacts at national meetings and institutions with NIH-funded T32 training programs, as well as members of scientific societies, and the research community)?

Program Oversight, Participating Faculty Selection, and Mentor Training

- Does the application describe an effective strategy and administrative structure to oversee and monitor the program to ensure appropriate and timely trainee progress for the duration of the trainees' undergraduate careers?
- Is selection of the program faculty based on a commitment to training and mentoring, and not simply research productivity?
- Will the participating faculty be trained to ensure the use of evidence-informed teaching and mentoring practices that promote the development of trainees from all backgrounds?
- Do the participating faculty have a record of employing the highest standards of rigor and transparency in their research, and plans to impart those standards to their trainees?
- Will the program ensure that program faculty reinforce and augment the curricular material on responsible conduct of research, and methods for enhancing reproducibility?
- Is there a clear mechanism for matching the trainees with appropriate program faculty?
- Is there a plan to ensure that the participating faculty engage in activities that promote trainee career development (including but not limited to the utilization of Individual Development Plans), and fulfill the need of the trainees to obtain their degrees in a timely fashion with the skills, credentials and experiences to transition into the next phase of the biomedical research pathway that are consistent with the trainees' interests, and values?
- Is there an effective mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing participating faculty displaying unacceptable mentorship qualities from the training program?
- If a program coordinator or administrator position is planned, will the person's administrative capabilities contribute to the success of the program?

Institutional and Departmental Commitment to the Program

- Will the institutional and departmental commitment to research and training excellence promote the success of the trainees and training program?
- Is there a clear institutional commitment to develop and promote a culture in which the highest standards of safety, scientific rigor, reproducibility, and responsible conduct of research are advanced?
- Does the institution provide sufficient start-up funding to permit early stage faculty to participate in training, and bridge funding to ensure that training may continue if a mentor experiences a hiatus in funds?
- Are the core facilities and technology resources necessary for the success of the program well supported?
- Is there adequate support of the PD(s)/PI(s) and other key staff, facilities, and educational resources associated with the training program?
- Do participating faculty have sufficient protected time available to devote to the training and mentoring activities?
- Is there evidence that the institution rewards excellence in training and mentoring through institutional policies?
- Does the institution support the remediation or removal of Participating Faculty from the program who are poorly performing mentors?
- Are diversity and inclusion efforts promoted at all levels of the research training environment (trainees, staff, faculty, and leadership)?

- Does the institution promote a positive, supportive, safe and inclusive research and training environment for individuals from all backgrounds?
- Is there evidence that the research facilities and laboratory practices ensure the safety of trainees?
- Is a process in place to address access issues for trainees with identified disabilities?
- Are appropriate policies and procedures in place to protect trainees from harassment and other prohibited practices?
- Is there evidence of an institutional commitment to providing the trainees access to student support services, such as health care, counseling services, and housing?
- Are the resources and expertise for evaluating the training outcomes of the program appropriate?
- Does the plan describe the changes the program(s), department(s) and/or the institution(s) will make to better support the goals of the training program?
- Does the application adequately address how research training at the undergraduate level is supported?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Do the PD(s)/PI(s) have the scientific expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Do the PD(s)/PI(s) have the time to commit sufficient effort to ensure the program's success, given their other professional obligations?
- Does at least one member of the PD/PI team have a demonstrated record of using rigorous and transparent methods in experimental design, data collection, analysis, and reporting in the proposed scientific field?
- Have the PD(s)/PI(s) received training on how to effectively mentor trainees, including those from underrepresented groups, and promote inclusive, safe, and supportive research training environments?
- Do the PD(s)/PI(s) have a demonstrated commitment to training the next generation of the biomedical research workforce, leading recruitment efforts to enhance diversity, and fostering inclusive research environments?
- Are there a strong administrative structure and leadership succession plan for critical positions (e.g., PD/PI)?

For applications designating multiple PD(s)/PI(s):

- Will the multiple PD/PI leadership approach benefit the trainees and enhance the ability of the program to achieve its training goals?
- Is there a clear leadership plan including the designated roles and responsibilities, governance, conflict resolution procedures, and organizational structure (see Multiple PD/PI Leadership Plan section)?

Preceptors/Mentors (Participating Faculty)

- Do the participating faculty describe a compelling commitment to rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results?
- Do the participating faculty describe a compelling commitment to ethically sound and responsible scientific research?
- Do the participating faculty have plans to promote the use of highest standards of practice to ensure the safety of all individuals in the research environment?
- Do the selected program faculty come from various backgrounds, for example, individuals from groups underrepresented in the biomedical sciences, women, as well as faculty at different career stages (i.e., junior and senior faculty)? If not, are there plans to recruit faculty to enhance the diversity?
- Do the participating faculty have the time to commit sufficient effort to ensure trainee development and success, given their other professional obligations?
- Is there evidence that the participating faculty cooperate, interact, and collaborate (which can include joint sponsorship of trainee research)?
- Do the participating faculty provide opportunities for trainees to initiate, conduct, interpret, and present rigorous and reproducible biomedical research with increasing self-direction?
- Do the participating faculty have plans for ensuring their trainees develop skills in approaches to experimental design, as well as methods of data collection, analysis, interpretation, and reporting?
- Do the participating faculty demonstrate a commitment to effective mentoring, and promoting inclusive, safe, and supportive scientific and training environments?
- Are the participating faculty willing to engage in activities to promote the trainees career goals and to support trainees participating in activities required to identify and transition into careers in the biomedical research workforce that are

consistent with the trainees' skills, interests, and values?
- Do the participating faculty have a commitment to fulfilling the need of the trainees to obtain their degrees in a timely fashion with the skills, credentials, and experiences to transition into research-focused higher degree programs (e.g., Ph.D. or M.D./Ph.D.)?

Trainee Positions, Appointment Process, and Retention, and Support

- Does the application provide a strong justification for the number of requested funded trainee positions given the pool of potential trainees, the size of the proposed program, the number of participating faculty, and other NIGMS funded training programs?
- Are trainees being appointed at the appropriate stage in order to most strongly benefit from the training program?
- Is the candidate review process likely to identify research-oriented candidates who are likely to transition to the next phase in the biomedical pathway?
- Is there an adequate, data-informed retention plan to ensure the well-being and success of all trainees throughout their training (see the "Trainee Retention Plan" attachment)?

Training Record

Training Outcomes for Trainees (renewals) or Training Grant Eligible Pool (new applications)

- Does the application provide evidence the trainees (or training grant eligible pool) conducted rigorous research that advanced scientific knowledge and/or technologies with increasing self-direction?
- Does the rate of degree attainment and time-to-degree for the trainees (or training grant eligible pool) indicate that these students completed their degrees at a high rate in a timely fashion?
- Are the trainees (or individuals in the training grant eligible pool) transitioning into and completing higher research-oriented higher degree programs (e.g., Ph.D. or M.D./Ph.D.)?

Program Evaluation

- Is there a well thought out evaluation or assessment plan to determine whether the overall program is effective in meeting its training mission and objectives, and whether the training and scientific research climates are inclusive and supportive of trainee development (narrative and "Evaluation and Assessment Instruments" Appendix)?
- Is there evidence that the program has been and/or will be responsive to outcomes, critiques and evaluations?
- Does the training program have an appropriate plan to track trainee outcomes and make the data publicly available (e.g., on the institution's website)?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Training in Methods for Enhancing Reproducibility

Does the Instruction in Methods for Enhancing Reproducibility plan describe how trainees will be instructed in principles important for enhancing research reproducibility including, at a minimum, evaluation of foundational research underlying a project, rigorous experimental design and data analysis, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, data and material sharing, record keeping, and transparency in reporting? Are the rigor and transparency components sufficiently well integrated into the overall curriculum? Are they taught at multiple stages of trainee development and in a variety of formats and contexts? Does the teaching synergize with elements of the curriculum designed to enhance trainees' abilities to conduct responsible research? Is there evidence that all participating faculty reiterate and augment key elements of methods for enhancing reproducibility when trainees are performing mentored research their laboratories? The plan will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee.

Recruitment Plan to Enhance Diversity

Reviewers will examine the strategies to be used in the recruitment of prospective individuals from underrepresented groups. The plan will be rated as ACCEPTABLE or UNACCEPTABLE, and the consensus of the review committee will be included in an

administrative note in the summary statement.

Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) **Format** - Does the plan satisfactorily address the format of instruction, e.g. lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (A plan involving only on-line instruction is not acceptable); 2) **Subject Matter** Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, and research ethics? 3) **Faculty Participation** - Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) **Duration of Instruction** - Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) **Frequency of Instruction** Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

Are the RCR components sufficiently well integrated into the overall curriculum? Are they taught at multiple stages of trainee development and in a variety of formats and contexts? Does the teaching of RCR synergize with elements of the curriculum designed to enhance trainees' abilities to conduct rigorous and reproducible research? Is there evidence that all participating faculty reiterate and augment key elements of responsible conduct when trainees are performing mentored research their laboratories?

Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project. Undue weight should not be given for simply responding to previous comments; instead the content of the responses and how the application project will be improved by any proposed changes should be considered.

Renewals

For Renewals, the committee will consider the progress made in the last funding period, including on the Training in Methods for Enhancing Reproducibility Plan, Recruitment Plan to Enhance Diversity, and Training in the Responsible Conduct of Research Plan.

- Did the training grant team successfully implement the proposed programmatic elements?
- Is the program achieving its training objectives?
- Is there evidence that the training environment is inclusive, safe, and supportive?
- Has the program evaluated the quality and effectiveness of the training experience, and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are changes proposed that are likely to improve or strengthen the research training experience during the next project period?

- Does the program continue to evolve to reflect changes in the research area in which the training occurs and current evidence-informed training and mentoring approaches?
- Is the program having a broader impact (e.g., are students beyond the trainees directly supported by the program being positively impacted by the program's presence, are training practices and outcomes being shared with the broader biomedical training community)?

Revisions

Not Applicable

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Select Agent Research

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the NIGMS Scientific Review (https://www.nigms.nih.gov/training/pages/ReviewProcess.aspx) Branch in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the NIGMS Advisory Council. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Geographic distribution of the NIGMS training grant portfolio.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (https://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html).

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov). For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html); https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf (https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).

- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the *NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=61170).

The taxability of stipends is described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=41171). Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=41171).

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the recipient institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11171) for additional information on this reporting requirement.

Other Reporting Requirements

- The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.php?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Recipients must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.php?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.

- A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.php?id=61189)). Individuals with a Conditional Permanent Resident status must first meet full (non-conditional) Permanent Residency requirements before receiving support.

A final RPPR and the expenditure data portion of the Federal Financial Report are required for closeout of an award as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11161).

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 Award Term and Conditions for Recipient Integrity and Performance Matters.

4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Trainees may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Within 10 years of making awards under this program, NIGMS will assess the program's overall outcomes.

The overall evaluation of the program will be based on metrics that will include, but are not limited to, the following:

- Institution types represented
- Geographical distribution of programs
- Demographics of trainees
- Trainee degree completion rates
- Time-to-degree
- Matriculation into and completion of research-oriented higher degree programs
- Scientific accomplishments of trainees
- Trainee career outcomes

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Commons Help Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)
Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726

Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

Kalynda Gonzales Stokes, Ph.D.
National Institutes of General Medical Sciences (NIGMS)
Email: kalynda.stokes@nih.gov (mailto:kalynda.stokes@nih.gov)

Lameese Akacem, Ph.D.
National Institutes of General Medical Sciences (NIGMS)
Email: lameese.akacem@nih.gov (mailto:lameese.akacem@nih.gov)

Peer Review Contact(s)

Stephanie Constant, Ph.D.
National Institute of General Medical Sciences
Email: stephanie.constant@nih.gov (mailto:stephanie.constant@nih.gov)

Financial/Grants Management Contact(s)

Justin Rosenzweig
National Institute of General Medical Sciences (NIGMS)
Email: rosenzwj@nigms.nih.gov (mailto:rosenzwj@nigms.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.php?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Authority and Regulations

Awards are made under the authorization of Section 487 of the Public Health Service Act as amended (42 USC 288) and under Federal Regulations 42 CFR 66.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?02-26-21)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

National Institutes of Health (/grants/oer.htm)
Office of Extramural Research
(https://www.hhs.gov/) Department of Health and Human Services (HHS)
USA.gov (https://www.usa.gov/)
NIH... Turning Discovery Into Health®

EXHIBIT B

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: [redacted]
Subject: [External] NIGMS Funding Update
Date: Wednesday, April 2, 2025 [redacted]

Re: [redacted]

Dear Dr. [redacted]

I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions. We advise against recruiting future cohorts.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include your grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

EXHIBIT C

This notice has expired. Check the NIH Guide (https://grants.nih.gov/funding/searchguide/) for active opportunities and notices.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Institute of General Medical Sciences (NIGMS (http://www.nigms.nih.gov))

Funding Opportunity Title

Initiative for Maximizing Student Development (IMSD) (T32 - Clinical Trial Not Allowed)

Activity Code

T32 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t32&Search.x=0&Search.y=0&Search_Type=Activity)
Institutional National Research Service Award (NRSA)

Announcement Type

Reissue of PAR-19-037 (https://grants.nih.gov/grants/guide/pa-files/par-19-037.html) - Initiative for Maximizing Student Development (IMSD) (T32)

Related Notices

- **November 14, 2023** - This PAR has been reissued as PAR-24-031 (//grants.nih.gov/grants/guide/pa-files/PAR-24-031.html)
- NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available
- **November 15, 2022** - Notice of a Question and Answer "Office Hour" with NIGMS Staff for IMSD and G-RISE Applicants. See Notice NOT-GM-23-020 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-23-020.html)
- **November 1, 2022** - Clarification of Eligibility for Institutions with Multiple Campuses in PAR-21-025 "Initiative for Maximizing Student Development (IMSD) (T32 - Clinical Trial Not Allowed)". See Notice NOT-GM-23-014 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-23-014.html)
- NOT-OD-22-190 (/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022
- **October 28, 2021** - Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 - New Grant Application Instructions Now Available. See Notice NOT-OD-22-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-018.html).
- **September 13, 2021** - Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice NOT-OD-21-181 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-181.html).
- **August 5, 2021** - New NIH "FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice NOT-OD-21-169 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-169.html)
- **August 5, 2021** - Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice NOT-OD-21-170 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-170.html)
- **April 20, 2021** - Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice NOT-OD-21-109 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-109.html)

EXPIRED

- **November 12, 2021** - Notice of Informational Webinar on the NIGMS IMSD and G-RISE Research Training Programs. See Notice NOT-GM-22-008 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-22-008.html).
- **May 28, 2021** - Notice of Change to the Instructions for Appendices in PAR-21-025. See Notice NOT-GM-21-047 (https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-047.html).
- **December 09, 2020** - Notice of Change to the Number of Applications that Can Be Submitted by Institutions Applying to PAR-21-025. See Notice NOT-GM-21-011 (/grants/guide/notice-files/NOT-GM-21-011.html).

Funding Opportunity Announcement (FOA) Number

PAR-21-025

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.859

Funding Opportunity Purpose

The goal of the Initiative for Maximizing Student Development (IMSD) program is to develop a diverse pool of scientists earning a Ph.D., who have the skills to successfully transition into careers in the biomedical research workforce. This funding opportunity announcement (FOA) provides support to eligible, domestic institutions to develop and implement effective, evidence-informed approaches to biomedical graduate training and mentoring that will keep pace with the rapid evolution of the biomedical research enterprise. NIGMS expects that the proposed research training programs will incorporate didactic, research, mentoring, and career development elements to prepare trainees for careers that will have a significant impact on the health-related research needs of the Nation. This program is limited to applications from training programs at research-intensive institutions (i.e., those with NIH Research Project Grant funding averaging greater than or equal to $7.5 million in total costs (direct and F&A/indirect) per year over the last three fiscal years).

This FOA does not allow appointed trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Key Dates

Posted Date

November 20, 2020

Open Date (Earliest Submission Date)

January 26, 2021

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

February 26, 2021; January 28, 2022; January 30, 2023, by 5:00 PM local time of applicant organization. All types of applications allowed for this funding opportunity announcement are due on these dates.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

June/July 2021, June/July 2022, June/July 2023

Advisory Council Review

October 2021; October 2022; October 2023

Earliest Start Date

February 2022, February 2023, February 2024

Expiration Date

January 31, 2023

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Training (T) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (NRSA) (//grants.nih.gov/grants/guide/url_redirect.htm?id=41125) website.

Purpose and Background Information

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Each program should provide high-quality research training, mentored research experiences, and additional training opportunities that equip trainees with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design and interpretation of data) and professional (e.g., management, leadership, communication, and teamwork) skills required for careers in the biomedical research workforce.

The National Institutes of Health (NIH) recognizes the need to diversify the scientific workforce by enhancing the participation of individuals from groups identified as underrepresented (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html) in the biomedical, clinical, behavioral and social sciences (collectively termed "biomedical") research workforce. Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual interests to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of research, enhancing public trust, and increasing the likelihood that health disparities and the needs of underserved populations are addressed in biomedical research.

NIGMS strives to ensure that future generations of researchers will be drawn from the entire pool of talented individuals, bringing different aptitudes, perspectives, interests, and experiences to address complex scientific problems. NIGMS seeks to enhance the diversity of the biomedical research workforce by supporting individuals from a variety of backgrounds at multiple training and career stages in a variety of institutions and educational settings across the country. Accordingly, NIGMS developed separate institutional eligibility tracks for review and funding of its undergraduate and graduate diversity enhancing programs based on NIH research project grant (RPG) (https://grants.nih.gov/grants/glossary.htm#ResearchProjectGrantRPG) funding levels. The two tracks include research-intensive, i.e., those with an average of NIH RPG funding greater than or equal to $7.5 million total costs per year over the past 3 fiscal years, and research-active, i.e., those with an average of RPG funding less than $7.5 million total costs per year over the past 3 fiscal years (RPG data are available through NIH RePORTER (https://report.nih.gov/award/index.cfm)). To prevent the duplication of diversity enhancing NIGMS programs, each institution will be eligible for one diversity enhancing undergraduate program (either Maximizing Access to Research Careers, MARC (https://www.nigms.nih.gov/training/marc/pages/ustarawards.aspx), or Undergraduate Research Training Initiative for Student Enhancement, U-RISE (https://www.nigms.nih.gov/training/RISE/Pages/U-RISE-T34.aspx)) regardless of the activity code (R25 or T34), and one diversity enhancing graduate program (either the Initiative to Maximize Student Development, IMSD (https://www.nigms.nih.gov/training/IMSD/pages/default.aspx), or G-RISE (https://www.nigms.nih.gov/training/RISE/Pages/G-RISE-T32.aspx)) regardless of the activity code (R25 or T32). Institutions with MARC, U-RISE, IMSD or G-RISE are eligible to participate in the Bridges to the Baccalaureate and/or Bridges to the Doctorate programs provided other eligibility requirements are met.

Need for the Program

In spite of recent advances, individuals from certain groups and backgrounds are underrepresented in the biomedical sciences research workforce as described in NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html). The severity of the underrepresentation of these groups increases throughout the training stages. For example in 2017, students from certain racial and ethnic groups, including Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders comprised ~35 percent of the college age population, but earned only ~25 percent of bachelor's degrees and ~16 percent of Ph.D. degrees in science and engineering (National Center for Science and Engineering Statistics (https://ncses.nsf.gov/pubs/nsb20197/demographic-attributes-of-s-e-degree-recipients#s-e-degrees-by-race-and-ethnicity)). Additionally, while the United States has seen a significant increase in the number of Ph.D. degrees in the biomedical

sciences earned by scientists from groups underrepresented in the biomedical research workforce, a corresponding increase in the ranks of the faculty in basic science departments at medical schools has not occurred (Gibbs, et al., 2016, eLife 2016, 5:e21393; Valantine, Lund & Gammie, CBE-Life Sciences Education, 2016, 15:fe4).

Several reports (see for example, ACD Working Group on Diversity in the Biomedical Workforce, 2012 (https://acd.od.nih.gov/documents/reports/DiversityBiomedicalResearchWorkforceReport.pdf); PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf); From College to Careers: Fostering Inclusion of Persons with Disabilities in STEM, 2014 (http://www.sciencemag.org/booklets/college-careers); and Increasing College Opportunity for Low Income Students, 2014 (https://obamawhitehouse.archives.gov/sites/default/files/docs/increasing_college_opportunity_for_low-income_students_report.pdf)) recommend supporting programs that strive to recruit, train, and mentor students from underrepresented groups who have an interest in science, technology, engineering and math (STEM) as a means to effectively build a diverse and competitive scientific workforce.

Programmatic Approach

This FOA is intended to enable the community to develop and implement evidence-informed approaches to biomedical research training and mentoring to enhance diversity in the biomedical research workforce. The President's Council of Advisors on Science and Technology (PCAST) report provided evidence that financial concerns and a deficit of peers from similar backgrounds can erode self-confidence and the will to remain in STEM majors (PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf)). NIGMS diversity enhancing institutional training grants offset the cost of appointed trainee stipends, tuition and fees, and training related expenses, including health insurance, in accordance with the approved NIH support levels. Additionally, funded programs are expected to provide activities that will build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members. Programmatic activities include, but are not limited to, providing authentic research experiences, academic enhancements, skills development, and additional mentoring - activities proven to increase persistence in STEM fields (cited in PCAST Report, 2012 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-engage-to-excel-final_2-25-12.pdf) and Graduate STEM Education for the 21st Century, 2018 (https://www.nap.edu/catalog/25038/graduate-stem-education-for-the-21st-century)). Each program should provide high-quality training that equips individuals with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design, and interpretation of data, conducting research in the safest manner possible) and professional (e.g., management, leadership, communication, and teamwork) skills required for careers in the biomedical research workforce. Funded programs are expected to promote inclusive research environments (i.e., institutional and departmental environments where trainees from all backgrounds feel integrated into and supported by the biomedical research community).

Program Objective

The Overarching Objective of this Initiative for Maximizing Student Development (IMSD) program is to develop a diverse pool of well-trained Ph.D. biomedical scientists, who have the following technical, operational, and professional skills:

- A broad understanding across biomedical disciplines and the skills to independently acquire the knowledge needed to advance their chosen fields;
- Expertise in a biomedical scientific discipline and the skills to think critically and independently, and to identify important biomedical research questions and approaches that push forward the boundaries of their areas of study;
- A strong foundation in scientific reasoning, rigorous research design, experimental methods, quantitative and computational approaches, and data analysis and interpretation;
- The skills to conduct research in the safest manner possible, and a commitment to approaching and conducting biomedical research responsibly, ethically, and with integrity;
- Experience initiating, conducting, interpreting, and presenting rigorous and reproducible biomedical research with increasing self-direction;
- The ability to work effectively in teams with colleagues from a variety of cultural and scientific backgrounds, and to promote inclusive and supportive scientific research environments;
- The skills to teach and communicate scientific research methodologies and findings to a wide variety of audiences (e.g., discipline-specific, across disciplines, and the public); and
- The knowledge, professional skills and experiences required to identify and transition into careers in the biomedical research workforce (i.e., the breadth of careers that sustain biomedical research in areas that are relevant to the NIH mission).

Diversity at all levels from the kinds of science to the regions in which it is conducted to the backgrounds of the people conducting it contributes to excellence in research training environments and strengthens the research enterprise. This FOA is intended to

support outstanding research training programs that will enhance diversity at all levels. As part of a larger initiative to enhance diversity, the IMSD program will support trainees earning a Ph.D. at research-intensive institutions.

Program Considerations

NIGMS intends to fund applications that propose feasible academic and research focused training programs that will enhance diversity in the biomedical workforce. Applicants are expected to identify training objectives (i.e., specific, measurable, and obtainable outcomes the program intends to achieve) and to develop plans to implement evidence-informed training and mentoring activities that are grounded in the literature and from evaluations of existing relevant programs. Program objectives must align with the overarching goal of the IMSD diversity enhancing program. Funded programs are expected to provide evidence of accomplishing the training objectives in progress reports and upon renewal, to make training and career outcomes publicly available, and are strongly encouraged to disseminate successful training practices to the broader community.

Institutional commitment and support for the proposed training program are important elements of the application. The IMSD program may complement and synergize with other ongoing federally-supported predoctoral research training programs at the applicant institution (e.g., in the development of skills needed for careers in the biomedical research workforce); however, the IMSD program goals and activities to achieve those goals must be distinct from related programs currently receiving federal support at the same institution. In cases where an institution has multiple NIGMS training grants, it is expected that these programs will seek to create administrative and training efficiencies to reduce costs and improve trainee services and outcomes. The training grant should be well integrated within one or more graduate department(s)/program(s) and should exert a strong, positive influence on the development and execution of the outreach and recruitment of potential trainees, graduate curriculum, training opportunities, and mentoring. Training grant funds may not be used solely as a vehicle to provide stipends for trainees to conduct research.

NIGMS does not accept applications for predoctoral T32 programs proposing only short-term research training. Programs proposing short-term research training should apply to the Kirschstein-NRSA Short-Term Institutional Research Training Grant Program (T35) exclusively reserved for predoctoral, short-term research training (see PA-20-162 (https://grants.nih.gov/grants/guide/pa-files/PA-20-162.html) and subsequent reissuances but note that NIGMS does not participate in that FOA). NIGMS will not accept applications proposing combined predoctoral and postdoctoral training under this FOA.

Training grants are usually awarded for five years. The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels. Students are typically provided full-time support for two to three years of graduate studies. Use of training grant support in the first three years of graduate research training is strongly encouraged to provide maximum flexibility in the participation in courses, laboratory rotations, professional development, and cohort-building activities.

This FOA does not allow appointed trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New

Resubmissions
Renewal of applications submitted to PAR-19-037 (https://grants.nih.gov/grants/guide/pa-files/par-19-037.html)

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials

Note: Appointed trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited but need to reflect the actual needs of the proposed project.

Grantees are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (*NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

NIGMS recognizes the need of trainees from diverse backgrounds, including those from underrepresented groups, to attend scientific meetings and/or training events, and to build professional networks. NIGMS will provide up to $1,000 per trainee per year to travel to scientific meetings or training experiences that will enhance scientific development, build science identity, create a sense of belonging in the scientific community, and build professional networks. Plans for trainee travel should be well justified. For IMSD-supported institutions outside the continental United States, $1,250 for travel per trainee per year will be provided.

Training Related Expenses

NIGMS will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, equipment, research supplies, and faculty/staff travel directly related to the research training program. Training related expenses are limited to a maximum of $6,400/trainee/year.

Allowable costs include those associated with the following:

Skills development training activities (e.g., focusing on quantitative and computational, problem-solving, critical thinking, scientific writing, effective communication, and project management);

Seminar speakers, who will serve as role models to the trainees

Training or mentoring interventions designed to increase persistence in research (e.g., those designed to increase science identity, self-efficacy and a sense of belonging in the scientific community);

Typically, salary support for the PD/PI or in a combination of multiple PD(s)/PI(s)/co-Investigators does not exceed 1.8 person months (i.e., 15% effort on a 12-month basis in total) depending on the size and scope of the program;

Salary support for administrative personnel; typically, the total combined salary support for program administrator/program coordinator and/or program assistant/clerical support does not exceed 3.0 person months (i.e., 25% effort on a 12-month basis) depending on the size and scope of the program.

Limited program evaluation costs (typically up to $3,000 for the 5-year training grant period) and other program-related expenses may be included within the budget for training-related expenses.

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of $25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIGMS does not permit automatic carryover from one budget period to the next. NIH grants policies as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Predominantly Black Institutions (PBI)
- Tribally Controlled Colleges and Universities (TCCUs)
- American Indian/Alaska Native Serving, Non-Tribal Institutions (AI/AN)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

For diversity enhancing programs, NIGMS recognizes separate institutional eligibility tracks: research-intensive, i.e., those with an average of NIH research project grant (RPG) (https://grants.nih.gov/grants/glossary.htm#ResearchProjectGrantRPG) funding greater than or equal to $7.5 million total costs per year over the past 3 fiscal years, and research-active, i.e., those with an average

of RPG funding less than $7.5 million total costs per year over the past 3 fiscal years (RPG data are available through NIH RePORTER (https://report.nih.gov/award/index.cfm)). For example, FY 2018, FY 2019 and FY 2020 for applications submitted in January 2021.

Institutional eligibility for this FOA is limited to research-intensive institutions as defined above. Research-active institutions are not eligible to apply for or receive IMSD grants. To prevent the duplication of NIGMS diversity enhancing programs, each institution is eligible for one undergraduate program (either MARC (https://www.nigms.nih.gov/training/marc/pages/ustarawards.aspx) or U-RISE (https://www.nigms.nih.gov/training/RISE/Pages/U-RISE-T34.aspx)) regardless of the activity code (R25 or T34), and one graduate program (either IMSD (https://www.nigms.nih.gov/training/IMSD/pages/default.aspx) or G-RISE (https://www.nigms.nih.gov/training/RISE/Pages/G-RISE-T32.aspx)) regardless of the activity code (R25 or T32). Institutions with NIGMS MARC, U-RISE, IMSD, or G-RISE funding are eligible for the Bridges to the Baccalaureate and/or Bridges to the Doctorate programs provided the other eligibility criteria are met.

An institution funded through the G-RISE or IMSD program that changes category due to changes in research project grant funding during the grant cycle should apply to the appropriate program based on their eligibility at the time of renewal. Programs that change category will report on the programs outcomes of the prior funding period(s), up to 15 years, using the appropriate tables.

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program should be detailed in the *Institutional Support Letter* in the **Letters of Support** attachment. Additionally, a signed letter is required from the Provost or similar official with institution-wide responsibility verifying the eligibility of the applicant institution at the time of application submission according to the eligibility criteria indicated above. See the application instructions for the required Letters of Support instructions in Section IV. (https://grants.nih.gov/grants/guide/pa-files/PAR-21-025.html#_Section_IV._Application)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy (//grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

As described in the instructions for the Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) in Section IV.2 below, NIGMS encourages multiple PDs/PIs, particularly when each brings a unique perspective and skill set that will enhance training. At least one of the training PDs/PIs should be an established investigator in the biomedical sciences and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. Additional PD(s)/PI(s), including individuals with experience in the science of education, relevant social science disciplines, program evaluation, mentoring, and university administration may be included to achieve the training goals. Any of the PDs/PIs may serve as the contact PD/PI. The contact PD/PI is expected to have a full-time appointment at the applicant institution unless extremely well-justified. If the full-time status of the contact PD/PI changes after the award, the institution must obtain prior program approval to appoint a new PD/PI or request a deviation from the full-time rule. The PDs/PIs will be responsible for the selection and appointment of trainees to the approved research training program, and for the overall direction, management, administration, and evaluation of the program. The PDs/PIs will be expected to monitor and assess the program and submit all documents and reports as required. The PDs/PIs have responsibility for the day-to-day administration of the program and are responsible for appointing members of the Advisory Committee (when applicable) and using their recommendations to determine the appropriate allotment of funds.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement*. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Preceptors/Mentors (Participating Faculty)

The selected faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support. When building a training team, programs should include faculty who are committed to training, mentoring, and providing supportive and inclusive research environments. Programs are encouraged to build a diverse team of preceptors/mentors that includes, for example, faculty from underrepresented groups (see Notice of NIH's Interest in Diversity) and faculty at different career stages (i.e., early-career as well as established faculty).

Trainees

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=61131).

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the NIH awarding unit. Use of training grant support in the first three years of graduate research training is strongly encouraged to provide maximum flexibility in the participation in courses, laboratory rotations, professional development, and cohort-building activities.

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The IMSD program is not intended for health-professional students who wish to interrupt their studies for a year or more to engage in research training.

Predoctoral trainees must be enrolled in a program leading to a Ph.D. in a biomedical discipline.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Training (T) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=61134) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

Follow all instructions provided in the SF424 (R&R) Application Guide.

SF424(R&R) Project/Performance Site Locations

Follow all instructions provided in the SF424 (R&R) Application.

SF424 (R&R) Other Project Information

Follow all instructions provided in the SF424 (R&R) Application, with the following additional modifications:

Are Human Subjects Involved: Check "No" unless the training program itself requires the trainees to take a workshop or course that will involve human subjects.

Are Vertebrate Animals Used: Check "No" unless the training program itself requires the trainees to take a workshop or course that will involve vertebrate animals.

Project Summary/Abstract. Provide an overview of the entire program. Include the mission, objectives, rationale and design of the research training program. Highlight key activities in the training plan that promote skills development and successful transitions into careers in the biomedical research workforce. Indicate the planned duration of appointments, the projected number of trainees and intended trainee outcomes.

Other Attachments.

Advisory Committee (1-page maximum). An Advisory Committee is not a required component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training program. The roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will assess the overall effectiveness of the program. To avoid conflicts in the review process, only pre-existing Advisory Committee members should be named in the application. Potential Advisory Committee members should not be identified or contacted prior to receiving an award. Please name the file Advisory_Committee.pdf .

Application and Admissions Data. The applicant must provide *Application and Admissions Data* to allow for the evaluation of the ability of participating departments/interdepartmental programs to recruit training grant eligible individuals. These data are useful

in assessing the admissions and recruitment process, the diversity of the pool, and the appropriate number of training positions to be awarded. Provide the numbers and characteristics of training grant eligible (I) applicants, (II) admitted individuals, and (III) matriculants for each of the past 5 academic years as well as the average over those years. Applicants are encouraged to use the Suggested Table Format Table A (https://www.nigms.nih.gov/training/instpredoc/Pages/predoctoral-nih-data-tables-data-formats.aspx) provided on the NIGMS website and to report on the categories listed in NIH s Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html) listed below. Demographic data should be from voluntary self-reporting.

- Total. The total number of individuals in the relevant category (e.g., applicants, admitted individuals, or matriculants). In cases of interdepartmental programs, provide aggregate data for all the participating departments.
- Number from Underrepresented Racial and Ethnic Minority (URM) Groups. Number of individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in biomedical research on a national basis (i.e., Black or African Americans, Hispanic or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders; see https://grants.nih.gov/grants/guide/notice-files/not-od-15-089.html (https://grants.nih.gov/grants/guide/notice-files/not-od-15-089.html))
- Number with a Disability. If data are available, the number with disabilities, defined as those with a physical or mental impairment that substantially limits one or more major life activities as described in the Americans with Disabilities Act of 1990, as amended (https://www.ada.gov/pubs/adastatute08.htm).
- Number from Disadvantaged Backgrounds. If data are available, the number from disadvantaged backgrounds (see NIH s Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)).
- Number of applicants who identify as women.
- Number of individuals from an institutionally defined underrepresented group. If relevant, number of applicants from a racial or ethnic group that can be demonstrated convincingly to be underrepresented by the grantee institution. For more information on racial and ethnic categories and definitions, see the OMB Revisions to the Standards for Classification of Federal Data on Race and Ethnicity (https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-28653.htm (https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-28653.htm)). Add columns as needed.

If the training program is interdepartmental with separate admissions for each department, provide the number of training grant eligible (I) applicants, (II) admitted individuals, and (III) matriculants in the relevant departments described in the application for each of the past 5 academic years. Please name the file Application_Admissions_Data.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Recruitment Plan to Enhance Diversity (3-page maximum). The applicant must provide a *Recruitment Plan to Enhance Diversity*. The application should include outreach strategies and activities designed to recruit potential training program candidates who are from diverse backgrounds, including students from underrepresented racial and ethnic groups, individuals with disabilities, and students from disadvantaged backgrounds (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)). Applicants are encouraged to consult the NIGMS webpage for strategies to enhance diversity in training programs (https://www.nigms.nih.gov/training/diversity/pages/approaches.aspx) when designing their plans. Describe the specific efforts to be undertaken by the training program and how these might coordinate with trainee recruitment efforts of the institution. Centralized institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups. Participating faculty are expected to be actively involved in recruitment efforts. Please name the file Recruitment_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Trainee Retention Plan (3-page maximum). The applicant must provide a *Trainee Retention Plan*. The *Trainee Retention Plan* must describe efforts to sustain the scientific interests as well as monitor the academic and research progress of trainees from all backgrounds within a program (i.e., retention). Applicants are encouraged to consult the NIH's extramural diversity website to identify promising retention practices (https://extramural-diversity.nih.gov/building-participation/recruitment-retention) and to use evidence-informed practices for retention with the recognition that the variety of trainee backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with trainee retention efforts of the institution(s). Centralized institutional efforts alone will not satisfy the requirement to implement robust and successful mechanisms to retain all trainees (e.g., participating faculty are expected to be actively involved in trainee retention efforts). Please name the file Retention_Plan.pdf . If this attachment is not included, the application will be considered incomplete and will not be reviewed.

Outcomes Data Collection and Storage Plan (2-page maximum). The applicant must provide an *Outcomes Data Collection and Storage Plan* to track the outcomes for all supported trainees for a minimum of 15 years beyond the trainee's participation in the program. Programs are encouraged to make the aggregate outcome data available on the institution's website. If the applicant

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Do not follow the organization and instructions provided in the SF424 (R&R) application guide for the Program Plan attachment; instead applicants must use the instructions below. Start each section with the appropriate heading.

Rationale, Mission, and Objectives

The application should describe how the IMSD program will develop a diverse pool of well-trained scientists who have the technical, operational, and professional skills required to conduct research in a safe, ethically responsible and rigorous manner, and to enter careers in the biomedical research workforce as delineated in the Program Objective. The application should describe how the program will enhance the training environment and not simply provide financial support to graduate trainees. Specifically, applicants should describe the following:

- The justification for the proposed diversity enhancing research training program. The application should describe the current institutional efforts to promote diversity and to create inclusive research training environments and how the IMSD program will enhance, but not duplicate these efforts. The rationale for the program should expand upon the "Training Outcome" data requested below that provides institutional baseline data on previous student outcomes comparing success rates for groups that are well-represented and underrepresented in the biomedical research workforce (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html));
- Current research training environment. The application should describe the research training environment including, but not limited to, the relevant background, an overview of the current research training activities of the participating department(s) or unit(s), and areas for improvement in the current research training practices. Applicants must demonstrate the presence of a sufficient number of potential trainees in appropriate disciplines (Table 1 (https://grants.nih.gov/grants/forms/data-tables.htm)) and program faculty with the appropriate biomedical expertise (Tables 2 and 4 (https://grants.nih.gov/grants/forms/data-tables.htm)) as well as the current research training resources (Table 3 (https://grants.nih.gov/grants/forms/data-tables.htm)); and
- The training mission (i.e., broad statement of purpose of the program), and objectives (i.e., specific measurable outcomes the program intends to achieve). The baseline data, the trainee pool, and the institutional context should inform the objectives and the design of the proposed training program. The program-specific mission and objectives should align with the Overarching Objective of this funding announcement. Objectives should include, but not be limited to, Ph.D. completion rates and appropriate time-to-degree.

Curriculum and Overall Training Plan

The application should describe the following:

- How the courses, structured activities, and research experiences will accomplish the specific training mission and objectives. Explain how these training activities are designed to develop the technical, operational, and professional skills of trainees. The application must include the "Required Training Activities" appendix to provide material to assess the required training elements and may use the "Elective Activities" appendix to provide up to four additional activities;
- Proposed changes to current research training practices to keep pace with the rapidly evolving biomedical research enterprise (e.g., curricular reforms, incorporation of additional quantitative and computational skills development, etc.);
- The mechanism for ensuring that the trainees are learning the highest standards of practice in biomedical research (e.g., record keeping and safety);
- How the Participating Faculty will teach laboratory safety throughout the didactic and mentored portions of the program;
- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, inclusion, and professional development;
- The activities that will build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members;
- Representative examples of training programs for individual trainees. Examples may include degree requirements, didactic courses, laboratory experiences, qualifying examinations, and other training activities, such as seminars, journal clubs, etc. Describe how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated. Discuss the anticipated time required to complete the training program up to degree attainment;
- The trainees academic and research background needed to pursue the proposed training and plans to accommodate differences in preparation among trainees (e.g., training and mentoring interventions provided in the summer before starting graduate courses and supplementary instruction throughout the training experience).
- How the training activities will be available to other trainees in the program(s), department(s) or institution(s) from which the supported trainees are drawn;

- For multi-disciplinary and/or multi-departmental programs, indicate how the individual disciplinary and/or departmental components of the program are integrated and coordinated, and how they will relate to an individual trainee's experience; and
- The ways, when applicable, that the training plan is distinct from, but will share resources and synergize with, other NIGMS-funded predoctoral training programs at the same institution (i.e., NIGMS predoctoral training programs listed in Table 3 (https://grants.nih.gov/grants/forms/data-tables.htm)). See the "Program Considerations" section above.

Career Development

The application should describe the following:

- How the pool of potential applicants and trainees will be provided with information about the career outcomes of graduates of the program (e.g., on publicly accessible websites) and about the overall biomedical research workforce employment landscape;
- How trainees in the program will be provided with adequate and appropriate information regarding the variety of careers in the biomedical research workforce for which their training would be useful;
- How the proposed program will engage a range of potential employers to ensure the trainees will acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them; and
- How the training program or institution will provide experiential learning opportunities (e.g., internships, shadowing, informational interviews, teaching opportunities) that allow trainees to develop the professional skills and networks necessary to transition into careers in the biomedical research workforce.

Program Oversight, Participating Faculty Selection, and Mentor Training

The application should include the planned strategy and administrative structure to oversee and monitor the program, and to ensure appropriate and timely trainee progress for the duration of the trainees' graduate careers (the application may include the "Evaluation and Assessment Instruments" Appendix to provide blank rubrics or forms). The application should describe how the participating faculty are trained to ensure the use of evidence-informed teaching, training and mentoring practices that promote the development of trainees from all backgrounds, e.g., trainees from underrepresented backgrounds in the biomedical sciences (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)). Applicants should describe the following:

- How the program will ensure that participating faculty employ the highest standards of scientific rigor and impart those standards to their trainees;
- How the program will ensure that participating faculty reinforce and augment the curricular material on responsible conduct of research, and methods for enhancing reproducibility;
- The mechanism for matching trainees with the appropriate participating faculty (e.g., laboratory rotations, faculty forums, and interviews);
- How the program will ensure that participating faculty engage in activities that promote trainee career development (including but not limited to the utilization of Individual Development Plans) and fulfill the need of the trainees to obtain their Ph.D. degrees in a timely fashion with the skills, credentials, and experiences to transition into careers in the biomedical research workforce that are consistent with the trainees interests and values;
- A mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty displaying unacceptable mentorship qualities from the training program (applicants may use the Appendix labeled Conflict Resolution Protocols to provide details of the plan); and
- If a program coordinator or administrator position is planned to enhance oversight, a description of the person's administrative capabilities that are essential to coordinate the program must be included in the application.

Institutional and Departmental Commitment to the Program

A letter providing assurances of the institutional commitment to the program must be included in the **"Letters of Support"** section of the application. Applicants may use this section to expand upon the Facilities & Other Resources section and the Letters of Support section, as necessary, to provide additional information regarding the institutional and departmental commitment to the program. Do not repeat information contained elsewhere in the application.

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) will promote the success of the trainees and training program. NIGMS encourages multiple PDs/PIs, particularly when each brings a unique perspective and skill set that will enhance training as described in the Eligible Individuals section. The application should expand on the information in the biosketch(es) to address how the PD/PI or PD/PI team has:

- The expertise, as well as the administrative and training experience, to provide strong leadership, direction, management, and administration of the proposed research training program;
- The time to commit sufficient effort to ensure the program's success given other professional obligations (the application should indicate the PD(s)/PI(s) s percent effort in the proposed program);
- At least one member of the team who has the scientific expertise in the biomedical sciences and who has a record of using rigorous and transparent methods in experimental design, data collection, analysis, and reporting;
- A demonstrated commitment to training the next generation of the biomedical research workforce, leading recruitment efforts to enhance diversity, and fostering inclusive research environments. As with all participating faculty, the PD(s)/PI(s) should have received training on how to effectively mentor trainees from all backgrounds, e.g., trainees from groups underrepresented in the biomedical sciences (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)); and
- A clearly delineated administrative structure and leadership succession plan for critical positions (e.g., PD(s)/PI(s)).

Preceptors/Mentors (Participating faculty)

The application should describe how the participating faculty will promote the success of the trainees and training program, as well as conducting responsible and rigorous research. Describe how the program has or will assemble a diverse team of participating faculty (e.g., individuals from underrepresented backgrounds (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-053.html)), women, and faculty at different career stages) to provide potential role models within the training program and to enhance the excellence of the training environment. The application should summarize and expand on the material presented in the Training Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and biosketches and address how the participating faculty:

- Have sufficient time to commit to training given their other professional obligations;
- Receive training in effective, evidence-informed teaching and mentoring practices;
- Promote the use of highest standards of practice to ensure the safety of all individuals in the research environment;
- Cooperate, interact, and collaborate (which can include joint sponsorship of trainee research);
- Promote the development of trainee skills in approaches to rigorous experimental design, methods of data collection, data analysis and interpretation, and reporting;
- Provide opportunities for trainees to initiate, conduct, interpret, and present rigorous, reproducible and responsible biomedical research with increasing self-direction;
- Demonstrate a commitment to effective mentoring, and to promoting inclusive, safe and supportive scientific and training environments; and
- Are evaluated as teachers and mentors.

Application Process, Trainee Positions, Retention, and Support

Through the narrative and summaries of the information presented in the required Training Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and the required attachments (i.e., *Application and Admissions Data* for all applications) the following areas relevant to trainees should be addressed.

Application Process

- Describe the admissions data provided in the required "Application and Admissions Data" attachment in "Other Attachments", including the characteristics of training grant eligible (I) applicants, (II) admitted individuals, and (III) matriculants for each of the past 5 academic years. Applicants are encouraged to report on the numbers and averages for the categories listed in NIH s Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html). If the program is an interdepartmental training program with separate admissions, describe the data in the required attachment regarding the number and averages of training grant eligible (I) applicants, (II) admitted individuals, and (III) matriculants in the relevant departments for each of the past 5 academic years. Application and admissions data should inform the recruitment plans in the training grant application.
- Expand upon the "Recruitment Plan to Enhance Diversity" (provided in "Other Attachments"). Explain how the program will identify and recruit a diverse pool of potential candidates from a wide variety of institutions and backgrounds (with a focus on identifying effective recruitment strategies for individuals from nationally underrepresented groups in the biomedical sciences,

see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) who have the potential to strongly benefit from, and with proper training and support succeed in the program.
- Describe plans for a candidate review process that will allow a broad group of trainees, who have taken advantage of the research opportunities available to them and are committed to contributing to the biomedical research enterprise, the ability to participate in the training program. The process should consider metrics beyond undergraduate institution, GPA, and standardized test scores. If the program trainees are drawn from multiple departments, describe how the PD(s)/PI(s) will ensure that the review process is consistent across all relevant departments.
- If the training program does not conduct its own recruitment and admissions for Ph.D. students entering the university and instead appoints students who were admitted by university departments or other graduate programs, provide a strong rationale for taking this approach.

Trainee Positions

- Describe how large the program will be *across all cohorts* (i.e., the total number of individuals enrolled in the proposed program ranging from the entering cohort to those nearing graduation). For interdepartmental programs, describe the expected number of individuals in the program from each scientific discipline.
- Provide a strong justification for the number of requested funded slots per year in the context of the training grant eligible pool, the size of the proposed program, the number of participating faculty, and other NIGMS-funded training grants at the institution. *For Renewal Applications* - Describe the characteristics of the previously awarded training positions (Table 7) as part of the justification for the requested positions.
- Explain the proposed training grant support structure, i.e., how many individuals (e.g., 4 per year), at what stage (e.g., first-year entrants), and for how long (e.g., for 1 year). Note: NIGMS typically funds trainees during years 1-3 of the Ph.D. program.
- Define and justify the selection and re-appointment criteria for the training grant supported trainees in the program.

Retention and Support

- Applicants may use this section to expand upon the Trainee Retention Plan (provided in the "Other Attachments") and to provide evidence of the program's commitment to ensuring the well-being and success of all trainees throughout their graduate training.
- Describe the ability for participating department(s) and/or the institution(s) to support trainees for the duration of their graduate careers.

Training Outcomes

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for training grant eligible students for the proposed program). The application should provide the information below about recent outcomes through narrative descriptions and a summary of the data presented in the required training tables (https://grants.nih.gov/grants/forms/data-tables.htm). Although the training tables for new applications only allow for five years of recent outcomes, the application may describe up to 15 years of outcomes in the narrative. The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications in Training Table 5A (https://grants.nih.gov/grants/forms/data-tables.htm), or other measures of scientific accomplishment appropriate to the field);
- The rate of Ph.D. degree attainment and time-to-degree for recent graduates (Training Table 8A (https://grants.nih.gov/grants/forms/data-tables.htm)). Verify in the text that the time-to-degree was calculated according to the table instructions;
- A description or analysis of how the Ph.D. degree attainment, time-to-degree data, and evidence of scholarly productivity (e.g., peer-reviewed publications, or other measures of scientific accomplishment appropriate to the field) for recent program graduates from underrepresented groups (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) compares to the data for recent program graduates from well-represented groups; and
- The success of recent graduates transitioning to careers in the biomedical research workforce (Training Table 8A (https://grants.nih.gov/grants/forms/data-tables.htm)).

Program Evaluation and Dissemination

NIGMS funded training programs must conduct ongoing evaluations to monitor the success of the training and mentoring activities. The application should describe:

- The evaluation or assessment process to determine whether the overall program is effective in meeting its training mission and objectives, and whether the scientific research climate is inclusive, safe, and supportive of trainee development (the application may include the "Evaluation and Assessment Instruments" Appendix to provide blank survey instruments, rubrics, or forms);
- Plans for being responsive to outcomes analyses, critiques, surveys and evaluations;
- Past activities to track and post the career outcomes of trainees (applicants should expand upon, but not duplicate the information in the Outcomes Data Collection and Storage Plan); and
- Past activities designed to share the outcomes of the training or mentoring interventions with the broader community (applicants should expand upon, but not duplicate the information in the Dissemination Plan).

Plan for Instruction in the Responsible Conduct of Research

Applicants are required to comply with the instructions for Plan for Instruction in the Responsible Conduct of Research as provided in the SF424 (R&R) Application Guide, along with the following additional instructions:

Describe how the Responsible Conduct of Research (RCR) components are well integrated into the overall curriculum, i.e., how they are taught at multiple stages of trainee development and in a variety of formats and contexts. Explain how the teaching of RCR synergizes with elements of the curriculum designed to enhance trainees abilities to conduct rigorous and reproducible research. Describe how all participating faculty will reiterate and augment key elements of responsible conduct when trainees are performing mentored research in their laboratories.

Plan for Instruction in Methods for Enhancing Reproducibility

Applicants are required to provide a Plan for Instruction in Methods for Enhancing Reproducibility as provided in the SF424 (R&R) Application Guide.

Applicants are encouraged to consult the NIGMS clearinghouse for training modules to enhance data reproducibility (https://www.nigms.nih.gov/training/pages/clearinghouse-for-training-modules-to-enhance-data-reproducibility.aspx) and other resources when developing the plans.

Progress Report (only for Renewal applications)

For applications describing programs that were previously funded under PAR-19-037 (https://grants.nih.gov/grants/guide/pa-files/par-19-037.html) follow the instructions provided in the SF424 (R&R) Application Guide with the following exceptions:

For the "Program Overview" section, follow the page limit indicated in the SF424 (R&R) application guide, but follow the instructions below instead:

- Indicate the period covered since the last competitive review.
- Include information to demonstrate that the program successfully trained a diverse pool of individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce.
- Describe successes and challenges with regards to implementing the programmatic elements described in the previous application, including but not limited to the following areas:

  o Incorporating evidence-informed training and mentoring practices into the program.

  o Teaching of rigor and transparency, and the responsible and safe conduct of research throughout the training experience.

  o The challenges and successes for enhancing diversity and inclusion.

  o Overseeing all aspects of the program (e.g., of the mentor/mentee matches, the participating faculty, and trainee progress).

  o Preparing trainees for a broad range of careers in the biomedical research workforce (including but not limited to the use of Individual Development Plans, IDPs).

- Provide justifications for failing to implement previously proposed programmatic elements.
- Provide evidence that the specific and measurable objectives described in the previous application were achieved and if not, provide a justification for failing to achieve the objectives.
- Describe how the funds provided under "Training Related Expenses" were used to benefit the program.
- Provide the methods and results of the evaluations of the program activities. Indicate whether the training activities were effective in contributing to the program objectives.
- Provide evidence that the scientific research climate is inclusive, safe, and supportive of trainee development.

- Expand upon the "Training Outcomes" to highlight successes and areas for improvement.
- Describe how the program responded to outcomes analyses, critiques, surveys and evaluations. Describe the barriers to success and indicate changes to the program designed to address these barriers.
- Describe how the program makes training and career outcomes publicly available.
- Indicate whether the PD(s)/PI(s) disseminated nationally any findings or materials developed under the auspices of the program to the broader training community.
- Indicate the broader impact of the program (e.g., on the curriculum, training environment, or institutional practices).
- Highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program.

Faculty, Trainees, and Training Record

Participating Faculty Biosketches

Participating faculty should provide a personal statement that describes the appropriateness of their research background for the proposed training program, and their commitment to the following:

- Training, mentoring, and promoting inclusive, safe and supportive research environments;
- Maintaining a record of, and providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results;
- Promoting the use of highest standards of practice to ensure the safety of all individuals in the research environment;
- Supporting trainees participating in activities required to identify and transition into careers in the biomedical research workforce that are consistent with the trainees skills, interests, and values; and
- Fulfilling the need of the trainees to complete their Ph.D. degrees in a timely fashion with the skills, credentials, and experiences to transition into careers in the biomedical research workforce.

Letters of Support

Institutional Support Letter (10-page maximum). The application must include a signed letter on institutional letterhead from a President, Provost, Dean, or similar key institutional leader that describes the activities and resources provided by the institution that are designed to ensure the success of the planned training program and its trainees. If this letter is not included, the application will be considered incomplete and will not be reviewed. The institutional commitment to the following areas should be described (as applicable):

- Developing and promoting a culture in which the highest standards of safety, scientific rigor, reproducibility, and responsible conduct are advanced;
- Ensuring sufficient start-up funding to permit early stage faculty to participate in training, and bridge funding to ensure that training may continue if a mentor experiences a hiatus in funds;
- Supporting core facilities and technology resources, and describing how they can be used to enhance training;
- Providing adequate staff, facilities, and educational resources to the planned program;
- Supporting the PDs/PIs and other key staff associated with the planned training program;
- Fostering and rewarding excellence in training (e.g., through institutional polices such as tenure and promotion);
- Supporting the remediation or removal of Participating Faculty from the program who are poorly performing mentors;
- Promoting diversity and inclusion at all levels of the research training environment (trainees, staff, faculty, and leadership);
- Ensuring a positive, supportive and inclusive research and training environment for individuals from all backgrounds;
- Ensuring the research facilities and laboratory practices promote the safety of trainees;
- Guaranteeing the research facilities are accessible to trainees with disabilities;
- Ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (e.g., requesting a change of PD/PI status; see NOT-OD-19-029 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-029.html));
- Providing trainees access to student support services, such as healthcare, counseling services, and housing;
- Ensuring that trainees will continue to be supported when they transition from the training grant to other sources of support;
- Providing resources and expertise for evaluating the training outcomes of the program; and
- For institutions that have multiple NIGMS-funded predoctoral training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones.

Institutional Eligibility Letter. (1-page maximum). The Provost or similar official with institution-wide responsibility must certify that all the components of the institution under the applicant DUNS or IPF number together have an average of RPG funding greater than or equal to $7.5 million total costs (both direct and F&A/indirect costs) per year over the past 3 fiscal years, as described in Section III, "Eligible Organization". If this letter is not included, the application will be considered incomplete and will not be reviewed.

Other Letters of Support. Additional letters of support (e.g., from partner institutions or organizations) are permitted; however, these letters may not contain any information required in the Institutional Support Letter.

Combine all Letters of Support into a single PDF file.

Data Tables: The application must include the required Training Data Tables (https://grants.nih.gov/grants/guide/url_redirect.htm?id=61169). For New applications: Tables 1, 2, 3, 4, 5A, and 8A Part III. For Renewals: Tables 1, 2, 3, 4, 5A, 7, and 8A. Applications that do not contain the required tables, or that submit any additional tables in this attachment, will be considered noncompliant and will not be reviewed.

Appendix

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to theSF424 (R&R) Application Guide instructions.

The Appendix is meant to provide additional details to the following topics but is not meant to substitute for clear descriptions in the body of the application. Do not use the Appendix to circumvent page limits. Do not include items other than the required and allowable materials described below, as doing so will result in administrative withdrawal of the application prior to review. Name the file according to the headings below. A summary sheet listing all the items included in the Appendix may be included in the first Appendix attachment.

The following are required Appendix materials:

- Required Training Activities. To adequately assess the content of the didactic portion of the training program, the application must include syllabi/outlines of all required training activities (e.g., syllabi for courses, mentor training materials, professional development workshops, career exploration opportunities, skills development activities).
- Responsible Conduct of Research Syllabi. In addition to the Plan for Instruction in the Responsible Conduct of Research, the application must provide syllabi/outlines of materials relating to Responsible Conduct of Research and descriptions of when in the trainees career paths the material is taught.

The following are allowable Appendix materials:

- Elective Activities. The application may include summary content from up to four additional elective courses and/or training activities (e.g., syllabi or summaries for courses, mentor training materials, outlines of professional development workshops, career exploration opportunities, or skills development activities).
- Evaluation and Assessment Instruments. The application may include blank surveys, rubrics, and/or forms used to (a) document and monitor trainee progress and (b) determine whether the training and research environment is effective, inclusive, safe, and supportive.
- Conflict Resolution Protocols (3-page maximum). The application may include detailed protocols for addressing problems with trainee and faculty matches, removal of faculty from the training program with unacceptable training/mentoring skills and for conflict resolutions for multi PD(s)/PI(s) and mentor/mentee relationships.

Applications that do not include the required appendices or that exceed the number of allowed appendices or the page limitation of any of the allowed materials will be considered noncompliant and will not be reviewed.

PHS Human Subjects and Clinical Trials Information

Generally, not applicable. All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional modifications:

Study Record: PHS Human Subjects and Clinical Trials Information

DO NOT USE. Attempts to submit a full, detailed study record will result in a validation error.

Delayed Onset Study

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Generally, not applicable. Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a program that will not start immediately (i.e., delayed start).

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120). The National Research Service Award (NRSA) policies (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your

control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH, and NIGMS. Applications that are incomplete or non-compliant will not be reviewed.

Applicants Requesting $500,000 or more for direct costs (less consortium F&A) in any year

Applicants requesting $500,000 or more in direct costs in any year **are not required** to contact a Scientific/ Research Contact prior to submitting an application. The Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide **is not** applicable to this FOA.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299).

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will produce a diverse pool of well-trained scientists with the technical (e.g., appropriate methods, technologies, and quantitative/computational approaches), operational (e.g., independent knowledge acquisition, rigorous experimental design, and interpretation of data), and professional (e.g., management, leadership, communication, and teamwork) skills necessary to conduct rigorous and reproducible research, and transition into careers in the biomedical research workforce, in consideration of the following review criteria and additional review criteria (as applicable for the program proposed).

Specifically, do the courses, structured training activities, mentoring, and research experiences equip the trainees with:

- A broad understanding across biomedical disciplines;
- Expertise in a basic biomedical scientific discipline and the skills to independently acquire the knowledge needed to advance their chosen fields;
- The ability to think critically and independently, and to identify important biomedical research questions and approaches that push forward the boundaries of their areas of study;
- A strong foundation in scientific reasoning, rigorous research design, experimental methods, quantitative and computational approaches, and data analysis and interpretation;
- The skills to conduct research in the safest manner possible, and a commitment to approaching biomedical research responsibly, ethically, and with integrity;
- Experience initiating, conducting, interpreting, and presenting rigorous and reproducible biomedical research with increasing self-direction;
- The ability to work effectively in teams with colleagues from a variety of cultural and scientific backgrounds, and to promote inclusive and supportive scientific research environments;

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- The skills to teach and communicate scientific research methodologies and findings to a wide variety of audiences (e.g., discipline-specific, across disciplines, and the public); and
- The knowledge, professional skills and experiences required to identify and transition into careers in the biomedical research workforce (i.e., the breadth of careers that sustain biomedical research in areas that are relevant to the NIH mission).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the training program and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Training Program and Environment

Rationale, Mission, and Objectives

- Does the application provide a compelling rationale for the proposed research training program?
- Does the proposed program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines (Table 1), program faculty with the appropriate scientific expertise (Tables 2 and 4), and resources to achieve the training objectives (Table 3)?
- Are the mission and objectives for the training program specific and measurable and in alignment with the goal of producing a diverse pool of well-trained scientists with the technical, operational, and professional skills necessary to transition into careers in the biomedical research workforce?

Curriculum and Overall Training Plan

- Will the courses, structured training activities, mentoring, and research experiences achieve the stated mission and objectives of the training program?
- Does the application propose changes in the program's research training and mentoring practices to effectively address the rapidly evolving biomedical research enterprise and current understanding of evidence-informed training and mentoring approaches?
- Is the mechanism for ensuring that the trainees are learning the highest standards of practice in biomedical research (e.g., record keeping and safety) robust?
- Will the Participating Faculty teach laboratory safety throughout the didactic and mentored portions of the program?
- Does the training program plan provide a compelling explanation of how the courses, structured training activities, mentoring, and research experiences employ modern, evidence-informed approaches that are likely to enhance the success of the trainees?
- Are the activities likely to build a strong cohort of research-oriented individuals while enhancing the science identity, self-efficacy, and a sense of belonging among the cohort members?
- Do the required and elective training elements (e.g., syllabi, course descriptions) provide compelling evidence that the trainees will gain the requisite skills for the discipline in a timely fashion and that there are mechanisms to ensure that the trainees will be guided, monitored, and evaluated?
- Are there plans to accommodate differences in preparation among trainees?
- Is it clear how the proposed program will enhance the research training environment and not simply provide financial assistance for the trainees?
- Is it clear how the training activities will be available to other students in the program(s), department(s), or institution(s) from which the trainees are drawn?
- For multi-disciplinary and/or multi-departmental programs, is it clear how the individual disciplinary and/or departmental components of the program are integrated and coordinated, and how each will relate to an individual trainee's experience?
- If applicable, is the proposed program distinct from, but planning to share resources and synergize with other NIGMS-funded predoctoral training programs at the institution (listed in Training Table 3, and reinforced in the Institutional Support Letter)?

Career Development

- Will the applicants and trainees be provided with information about the career outcomes of graduates of the program and about the overall biomedical research workforce employment landscape?
- Will the trainees be provided with adequate and appropriate information regarding the wide variety of careers in the biomedical research workforce for which their training may be useful?
- Will the program engage with potential employers to ensure that the trainees acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them?
- Will the training program or institution provide experiential learning opportunities (e.g. internships, shadowing, informational interviews) that allow trainees to develop the professional skills and networks necessary to transition into careers in the biomedical research workforce?

Program Oversight, Participating Faculty Selection, and Mentor Training

- Does the application describe an effective strategy and administrative structure to oversee and monitor the program to ensure appropriate and timely trainee progress for the duration of the trainees' graduate careers?
- Is selection of the program faculty based on a commitment to training and mentoring, and not simply research productivity?
- Will the participating faculty be trained to ensure the use of evidence-informed teaching and mentoring practices that promote the development of trainees from all backgrounds?
- Do the participating faculty have a record of employing the highest standards of rigor and transparency in their research, and plans to impart those standards to their trainees?
- Will the program ensure that program faculty reinforce and augment the curricular material on responsible conduct of research, and methods for enhancing reproducibility?
- Is there a clear mechanism for matching the trainees with appropriate program faculty (e.g., laboratory rotations, faculty forums and interviews)?
- Is there a plan to ensure that the participating faculty engage in activities that promote trainee career development (including but not limited to the utilization of Individual Development Plans), and fulfill the need of the trainees to obtain their Ph.D. degrees in a timely fashion with the skills, credentials and experiences to transition into careers in the biomedical research workforce that are consistent with the trainees' interests, and values?
- Is there an effective mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing participating faculty displaying unacceptable mentorship qualities from the training program?
- If a program coordinator or administrator position is planned, will the person's administrative capabilities contribute to the success of the program?

Institutional and Departmental Commitment to the Program

- Will the institutional and departmental commitment to research and training excellence promote the success of the trainees and training program?
- Is there a clear institutional commitment to develop and promote a culture in which the highest standards of safety, scientific rigor, reproducibility, and responsible conduct of research are advanced?
- Does the institution provide sufficient start-up funding to permit early stage faculty to participate in training, and bridge funding to ensure that training may continue if a mentor experiences a hiatus in funds?
- Are the core facilities and technology resources necessary for the success of the program well supported?
- Is there adequate support of the PD(s)/PI(s) and other key staff, facilities, and educational resources associated with the training program?
- Do participating faculty have sufficient protected time available to devote to the training and mentoring activities?
- Is there evidence that the institution rewards excellence in training and mentoring through institutional policies?
- Does the institution support the remediation or removal of Participating Faculty from the program who are poorly performing mentors?
- Are diversity and inclusion efforts promoted at all levels of the research training environment (trainees, staff, faculty, and leadership)?
- Does the institution promote a positive, supportive, safe and inclusive research and training environment for individuals from all backgrounds?
- Is there evidence that the research facilities and laboratory practices ensure the safety of trainees?
- Is a process in place to address access issues for trainees with identified disabilities?
- Are appropriate policies and procedures in place to protect trainees from harassment and other prohibited practices?

- Is there evidence of an institutional commitment to providing the trainees access to student support services, such as health care, counseling services, and housing?
- Is there a commitment to ensure that trainees will continue to be supported when they transition from the training grant to other sources of support?
- Are the resources and expertise for evaluating the current and future training outcomes of the program appropriate?
- Does the program plan describe the changes the graduate program(s), department(s) and/or the institution(s) will make to better support the goals of the training program?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Do the PD(s)/PI(s) have the scientific expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Do the PD(s)/PI(s) have the time to commit sufficient effort to ensure the program's success, given their other professional obligations?
- Does at least one member of the PD/PI team have a demonstrated record of using rigorous and transparent methods in experimental design, data collection, analysis, and reporting in the proposed scientific field?
- Have the PD(s)/PI(s) received training on how to effectively mentor trainees, including those from underrepresented groups, and promote inclusive, safe, and supportive research training environments?
- Do the PD(s)/PI(s) have a demonstrated commitment to training the next generation of the biomedical research workforce, leading recruitment efforts to enhance diversity, and fostering inclusive research environments?
- Is there a strong administrative structure and leadership succession plan for critical positions (e.g., PD/PI)?

For applications designating multiple PD(s)/PI(s):

- Will the multiple PD/PI leadership approach benefit the trainees and enhance the ability of the program to achieve its training goals?
- Is there a clear leadership plan including the designated roles and responsibilities, governance, conflict resolution procedures, and organizational structure (see Multiple PD/PI Leadership Plan section)?

Preceptors/Mentors (Participating Faculty)

- Do the participating faculty describe a compelling commitment to rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results?
- Do the participating faculty describe a compelling commitment to ethically sound and responsible scientific research?
- Do the participating faculty have plans to promote the use of highest standards of practice to ensure the safety of all individuals in the research environment?
- Do the selected program faculty come from various backgrounds, for example, individuals from groups underrepresented in the biomedical sciences, women, as well as faculty at different career stages (i.e., junior and senior faculty)? If not, are there plans to recruit faculty to enhance the diversity?
- Do the participating faculty have the time to commit sufficient effort to ensure trainee development and success, given their other professional obligations?
- Is there evidence that the participating faculty cooperate, interact, and collaborate (which can include joint sponsorship of trainee research)?
- Do the participating faculty provide opportunities for trainees to initiate, conduct, interpret, and present rigorous and reproducible biomedical research with increasing self-direction?
- Do the participating faculty have plans for ensuring their trainees develop skills in approaches to experimental design, as well as methods of data collection, analysis, interpretation, and reporting?
- Do the participating faculty demonstrate a commitment to effective mentoring, and promoting inclusive, safe, and supportive scientific and training environments?
- Are the participating faculty willing to engage in activities to promote the trainees career goals and to support trainees participating in activities required to identify and transition into careers in the biomedical research workforce that are consistent with the trainees' skills, interests, and values?
- Do the participating faculty have a commitment to fulfilling the need of the trainees to obtain their Ph.D. degrees in a timely fashion with the skills, credentials, and experiences to transition into careers in the biomedical research workforce?

Application Process, Trainee Positions, Retention, and Support

Application Process

- Is a candidate review process proposed that will allow a broad group of trainees, who have taken advantage of the research opportunities available to them and are committed to contributing to the biomedical research enterprise, the ability to participate in the training program? Does the process consider metrics beyond undergraduate institution, GPA, and standardized test scores?
- If the program trainees are drawn from multiple departments, is the review process consistent across all relevant departments?
- Is the training program's approach to recruiting and admitting students appropriate (e.g., direct admissions as first year Ph.D. students into the program versus appointment of students admitted to other departments or Ph.D. programs)?

Funded Positions

- Does the application provide a strong justification for the number of requested funded trainee positions given the pool of potential trainees, the size of the proposed program, the number of participating faculty, and other NIGMS funded training programs?
- Are there well-defined and justified selection and re-appointment criteria for trainees in the training program?
- Are trainees being appointed at the appropriate stage in order to most strongly benefit from the training program (e.g., in the first three years)?

Retention and Support

- Is there an adequate, evidence-informed retention plan to ensure the well-being and success of all trainees throughout their graduate training (see the "Trainee Retention Plan" attachment)?
- Does the institution have the resources to support trainees for the duration of their graduate careers?

Training Record

Training Outcomes for Trainees (renewals) or Training Grant Eligible Pool (new applications)

- Does the application provide evidence the trainees (or training grant eligible pool) conducted rigorous research that advanced scientific knowledge and/or technologies with increasing self-direction (e.g., peer-reviewed publications listed in Table 5A, and other accomplishments appropriate to the field)?
- Does the rate of Ph.D. degree attainment and time-to-degree for the trainees (or training grant eligible pool) indicate that these students completed their degrees at a high rate in a timely fashion (Training Table 8A)?
- Are completion rates, time-to-degree, and scholarly outcomes for the trainees (or training grant eligible pool) from underrepresented groups (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) comparable to those from well-represented groups?
- Are the trainees (or individuals in the training grant eligible pool) transitioning to careers in the biomedical research workforce (i.e., the breadth of careers involved in the conduct and support of biomedical research in areas that are relevant to the NIH mission; Training Table 8A)?

Program Evaluation

- Is there a well thought out evaluation or assessment plan to determine whether the overall program is effective in meeting its training mission and objectives, and whether the training and scientific research climates are inclusive and supportive of trainee development (narrative and "Evaluation and Assessment Instruments" Appendix)?
- Is there evidence that the program has been and/or will be responsive to outcomes, critiques and evaluations?
- Does the training program have an appropriate plan to track trainee outcomes and make the data publicly available (e.g., on the institution's website)?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Training in Methods for Enhancing Reproducibility

Does the Instruction in Methods for Enhancing Reproducibility plan describe how trainees will be instructed in principles important for enhancing research reproducibility including, at a minimum, evaluation of foundational research underlying a project, rigorous experimental design and data analysis, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, data and material sharing, record keeping, and transparency in reporting? Are the rigor and transparency components sufficiently well integrated into the overall curriculum? Are they taught at multiple stages of trainee development and in a variety of formats and contexts? Does the teaching synergize with elements of the curriculum designed to enhance trainees' abilities to conduct responsible research? Is there evidence that all participating faculty reiterate and augment key elements of methods for enhancing reproducibility when trainees are performing mentored in research their laboratories? The plan will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee.

Recruitment Plan to Enhance Diversity

Peer reviewers will separately evaluate the recruitment plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of prospective individuals from underrepresented groups. The plan will be rated as ACCEPTABLE or UNACCEPTABLE, and the consensus of the review committee will be included in an administrative note in the summary statement.

Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) **Format** - Does the plan satisfactorily address the format of instruction, e.g. lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (A plan involving only on-line instruction is not acceptable); 2) **Subject Matter** Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, and research ethics? 3) **Faculty Participation** - Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) **Duration of Instruction** - Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) **Frequency of Instruction** Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

Are the RCR components sufficiently well integrated into the overall curriculum? Are they taught at multiple stages of trainee development and in a variety of formats and contexts? Does the teaching of RCR synergize with elements of the curriculum designed to enhance trainees' abilities to conduct rigorous and reproducible research? Is there evidence that all participating faculty reiterate and augment key elements of responsible conduct when trainees are performing mentored research their laboratories?

Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Resubmissions

A0967

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project. Undue weight should not be given for simply responding to previous comments; instead the content of the responses and how the application project will be improved by any proposed changes should be considered.

Renewals

For Renewals, the committee will consider the progress made in the last funding period, including on the Training in Methods for Enhancing Reproducibility Plan, Recruitment Plan to Enhance Diversity, and Training in the Responsible Conduct of Research Plan.

- Did the training grant team successfully implement the proposed programmatic elements?
- Is the program achieving its training objectives?
- Is there evidence that the training environment is inclusive, safe, and supportive?
- Has the program evaluated the quality and effectiveness of the training experience, and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are changes proposed that are likely to improve or strengthen the research training experience during the next project period?
- Does the program continue to evolve to reflect changes in the research area in which the training occurs and current evidence-informed training and mentoring approaches?
- Is the program having a broader impact (e.g., are students beyond the trainees directly supported by the program being positively impacted by the program's presence, are training practices and outcomes being shared with the broader biomedical training community)?

Revisions

Not Applicable

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Select Agent Research

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the NIGMS Scientific Review (https://www.nigms.nih.gov/training/pages/ReviewProcess.aspx) Branch in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the National Advisory General Medical Sciences Council. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

- Geographic distribution of the NIGMS training grant portfolio.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (https://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html).

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator s scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov). For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for

Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
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- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html); https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf (https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the *NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=61170).

The taxability of stipends is described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171). Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171).

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the grantee institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award.

A0970

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

Other Reporting Requirements

- The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.htm?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Grantees must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.htm?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.
- A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.htm?id=61189)). Individuals with a Conditional Permanent Resident status must first meet full (non-conditional) Permanent Residency requirements before receiving support.
- Termination Notice: Within 30 days of the end of the total support period, the institution must submit a Termination Notice (PHS Form 416-7 (//grants.nih.gov/grants/guide/url_redirect.htm?id=41179)) via xTrain (//grants.nih.gov/grants/guide/url_redirect.htm?id=41183) for each trainee appointed for eight weeks or more.

A final RPPR, the expenditure data portion of the Federal Financial Report, and Termination Notices for all Trainees, are required for closeout of an award as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 Award Term and Conditions for Recipient Integrity and Performance Matters.

4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Trainees may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Within 10 years of making awards under this program, NIGMS will assess the program's overall outcomes.

The overall evaluation of the program will be based on metrics that will include, but are not limited to, the following:

- Institution types represented
- Geographical distribution of programs
- Demographics of trainees
- Trainee Ph.D. completion rates
- Time-to-degree
- Scientific accomplishments of trainees
- Trainee career outcomes

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Commons Help Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)
Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

Shakira Nelson, Ph.D.
National Institute of General Medical Sciences (NIGMS)
Email: shakira.nelson@nih.gov (mailto:shakira.nelson@nih.gov)

Mercedes Rubio, Ph.D.
National Institute of General Medical Sciences (NIGMS)
Email: rubiome@mail.nih.gov (mailto:rubiome@mail.nih.gov)

Peer Review Contact(s)

Stephanie Constant, Ph.D.
National Institute of General Medical Sciences
Email: stephanie.constant@nih.gov (mailto:stephanie.constant@nih.gov)

Financial/Grants Management Contact(s)

Justin Rosenzweig
National Institute of General Medical Sciences
Email: rosenzwj@nigms.nih.gov (mailto:rosenzwj@nigms.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Section 487 of the Public Health Service Act as amended (42 USC 288) and under Federal Regulations 42 CFR 66.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?11-20-20)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

NIH National Institutes of Health (/grants/oer.htm)
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A0972

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NIH... Turning Discovery Into Health®

EXHIBIT D

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: [redacted]
Subject: [External] NIGMS Funding Update
Date: Wednesday, April 2, 2025 [redacted]

Re: [redacted]

Dear Dr. [redacted]

I am writing to let you know that due to changes in NIH/HHS priorities, the **Initiative for Maximizing Student Development (IMSD)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions. We advise against recruiting future cohorts.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include your grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF KELLY BLANCHARD

I, Kelly Blanchard, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. I am the President of Ibis Reproductive Health (Ibis). I have served in that role since November 2004. Founded in 2002, Ibis is a global research organization whose mission is to drive change through bold, rigorous research and principled partnerships that advance sexual and reproductive autonomy, choice, and health worldwide.
2. I make this declaration on behalf of Ibis Reproductive Health in support of its Motion for Preliminary Injunction seeking to enjoin defendants from implementing or enforcing unlawful directives, and terminations of grants that supposedly no longer effectuate agency priorities, including research grant R01HD109320, which was terminated by the NIH in March 2025.
3. I have extensive training and experience in clinical and social science research and have led clinical trials and other qualitative and quantitative research for more than 20 years. I earned an MSc in Population and International Health from the Harvard School of Public Health and an AB from

Harvard College. I have published more than 140 articles in peer-reviewed scientific journals and serve as an expert peer reviewer for high-impact journals. Since 2004 as President of Ibis Reproductive Health I have provided strategic leadership of the organization and worked with our Senior Management Team to lead cutting edge research, build and maintain the critical principled partnerships to develop and implement that research, raise the funding needed to undertake this work, and disseminate and communicate research results to key stakeholders, including policy makers, clinicians, professional societies and norm setting bodies, and the general public to ensure our research and project work makes an impact.

Award of NIH Grant R01HD109320

1. Public health research is core to Ibis's work, which is informed by relationships and collaboration with communities, including transgender and gender diverse community members, to identify key gaps in information and resources concerning reproductive health, autonomy, and health care access for these populations. With offices in Cambridge, Massachusetts, Oakland, California, and Johannesburg, South Africa, Ibis has a highly trained and committed staff of demographers, epidemiologists, and public health researchers leading over 30 studies worldwide.
2. In September 2023, Ibis was awarded a National Institutes of Health ("NIH") Grant R01HD109320 titled "*Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality*" based on a panel of expert reviewers scoring the proposal in the top 2 percent of all submitted grants that cycle for its likelihood of exerting a sustained and positive impact on public health. A true and correct copy of this Notice of Award (NOA) is attached as **Exhibit A**. This five-year research grant anticipated providing approximately $2.2

million in funding[1] for a research project to evaluate innovative methods for improving the collection and quality of data in sexual and reproductive health (SRH) research for all people, including those who identify as transgender and gender diverse.

3. NIH Grant R01HD109320 was awarded to support the goal of enhancing research on the sexual and reproductive health of transgender, nonbinary, and intersex people (TNBI) people. The Institute of Medicine's report on "The Health of Lesbian, Bisexual, and Transgender People," called for NIH-supported research to address the methodological challenges that have impeded research on the health of transgender people – specifically, to improve strategies for reaching larger, more diverse samples of transgender persons in the United States. Historically, research on SRH has excluded or misclassified TNBI people due to presumptions that pregnancy and related outcomes can be experienced solely by cisgender women. However, TNBI people plan for and carry pregnancies, and thus require high-quality and evidence-based healthcare. Despite this need, existing data on the SRH needs of TNBI populations primarily come from convenience samples – small in size and/or limited in geographic scope. The dearth of representative data has meant, critically, that SRH providers do not have adequate evidence upon which to rely to ensure that the SRH needs of their TNBI patients are met within existing healthcare services – thereby contributing to lower quality care and SRH disparities among these populations.

4. With the Grant, Ibis intended to test methods of improving the representativeness of the research population, participant retention, and quality of collected data among TNBI people in the United States. Specifically, the research project sought to (1) recruit a large, diverse sample of TNBI people from across the United States, (2) collect longitudinal data on core SRH outcomes (virtually

[1] The Notice of Award provided the following recommended total awards for each year of the grant: YR 1 ($510,937); YR 2 ($482,443); YR 3 ($434,712); YR 4 ($424,119(; YR 5 ($405, 474).

no longitudinal data on these topics exist among TNBI people), and (3) improve retention and data quality among TNBI participants in SRH research as compared to standard methods.

5. Additionally, the research project sought to further a cross-cutting goal identified by the National Institute of Child Health and Human Development's (NICHD) 2020 and 2025 Strategic Plans – to address health disparities for sexual and gender minority people – and would have contributed evidence toward "Advancing Gynecologic, Andrologic, and Reproductive Health" and "Setting the Foundation for Healthy Pregnancies and Lifelong Wellness", two of the five core priorities of the NICHD 2025 Strategic Plan. The Grant went through a noncompetitive renewal process, and was renewed for the June 1, 2024 – May 31, 2025 budget cycle. A true and correct copy of this NOA, renewing the Grant is attached as **Exhibit B**. Per the standard noncompetitive renewal process, the Principal Investigator submitted a Research Performance Progress Report (RPPR) six weeks before the end of the first grant year, and after review by NICHD staff, the study was determined to be proceeding appropriately, and thus the second year of the Grant was awarded.
6. In addition to the primary research Grant, Ibis was awarded a supplemental grant for years 2 through 5 of the study, tied to the R01 Grant, which provided an additional $59,000 of funding per year. A true and correct copy of this supplemental award is attached as **Exhibit C**.
7. The preparation of this grant application took several years. The first conversation with a Program Officer at the NIH to begin development of this grant application took place in January 2019. The final revised R01 application was the result of over two years of conceptualization, relationship building, study design, drafting, and multiple expert consultations. The first draft of the application was submitted to the NICHD in October 2021. It was not funded and received reviewer feedback. The Principal Investigator then worked to revise the application based on those comments, with members of the research project team and partners in additional rounds of expert consultation and

review, alongside input from the NICHD Program Officer. These revisions took another six months before readiness for submission of the final revised application in July 2022, which was ultimately funded in September of 2023 - over four and a half years after preparation of the application first began.

8. Ibis's proposed research project was reviewed by a study section which scored the proposed project in the highest 2 percent of reviewed proposals. In the Summary Statement submitted by the panel of scientists, expert reviewers characterized the research as being "exceptionally high impact and has a high likelihood of profound and sustained impact on public health research and clinical practice" as well as having the potential to "significantly change the field by establishing new tools for assessing the relevance of key preventative health screenings in public health research and clinical practice," and that the study would "fill a massive gap in terms of research."
9. To the extent that the termination of this grant has prevented the collection of survey data, each week that goes by is another week where people are not being appropriately screened into clinical care and research that would be relevant for their bodies, leading to missed preventative care, or conversely, unnecessary preventive care. The screening tools the surveys would have tested were designed to identify improvements to clinical and research screening questions that could address these discordances. Further, each week that goes by without the contribution of this data to the field is a week where clinical providers do not have the evidence they need to provide evidence-based SRH care to TNBI people, including care related to fertility services, pregnancy, family formation, contraceptive use, and more. Leading professional and medical societies have emphasized the urgent need for these data, as have Americans who deserve to see themselves reflected in the research.

10. In the nearly two years since the Grant was awarded, Ibis has hired two full-time staff to serve as research coordinators and has invested thousands of staff hours in developing essential components of the research project – namely the various survey designs and methodologies to be tested for their ability to improve accuracy, completion, and quality of survey data. This work has included recruiting, convening, and seeking input from community advisory board members; conducting formative cognitive interviews; developing and programming a complex, highly novel and innovative online survey with randomization of key survey methodologies to be tested, formalizing research project partnerships with academic institutions and community partners; and seeking and securing institutional review board (IRB) approval of the research. The research team was poised to launch the first of several surveys and begin full data collection shortly after the termination letter was received.

Termination of NIH Grant R01HD109320

11. On March 20, 2025, in the midst of the second year of grant funding, I received a letter from the NIH notifying me that the funding for R01HD109320 was terminated. The termination letter stated that the R01HD109320 Grant "no longer effectuates agency priorities." The letter goes on to state that "[r]esearch programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. It is the policy of NIH not to prioritize these research programs . . . The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities." A true and correct copy of this termination letter is attached as **Exhibit D**. The letter was signed by Michelle G. Bulls on behalf of Margaret Young, Chief Grants Management Officer for the NICHD.

12. I was not given any previous indication by NIH, the Institute, or the Program Officer that Ibis's R01HD109320 Grant was in jeopardy of being terminated.

13. The termination letter was vague and not scientifically accurate, nor does it explain how the agency decision was made or consider important aspects of the funded research. For example, the termination letter does not give a description of what is meant by "gender identity," nor was Ibis provided any clarification on why the grant was terminated based on the belief that "[r]esearch programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans." Existing research does not support this statement, and indeed, the panel of experts convened by the NIH concluded the opposite, that this research had a strong likelihood of exerting "profound and sustained impact on public health" for Americans.

14. On March 26, 2025, I received revised NOAs for both the primary grant [5R01HD109320-02] and the supplemental grant [3R01HD109320-02S1] indicating that the end of each grant was revised to March 21, 2025. True and correct copies of these revised NOAs are attached as **Exhibit E** and **Exhibit F**. These revised NOAs repeated the vague and inaccurate statement from the termination letter, and provided limited instructions for the close out of the Grant.

15. The implementation of this Grant to date has been in full compliance with the terms and conditions of the award, and the research is in full alignment with the stated priorities of the NIH broadly, and the NICHD specifically. Nor has Ibis provided consent for the termination.

16. The abrupt decision during an awarded grant year unjustly disrupts vital research with significant public health implications, and causes harm to Ibis's small, nonprofit research organization and its research project partners. As a result of the Grant termination in the midst of a grant year, Ibis is suddenly left without funding to support commitments to staff salary and benefits, and subaward

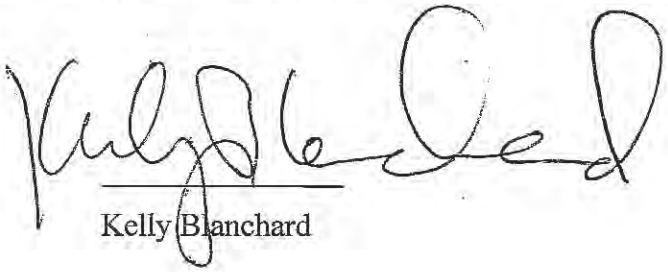
costs. Ibis cannot complete the urgently needed research that the NIH has already invested $1,047,555 over the past 22 months, leading to a potentially significant wasted investment. Additionally, the $1.4 million in research funding committed to Ibis in the NOA for the remaining 3-5 years of the grant was an important part of the $8 million annual operating budget for Ibis, as a small nonprofit organization.

17. As a result of the grant termination, Ibis must restructure research teams because of staffing pressures and seek additional funding to cover the salaries of four employees staffed on the project. This termination potentially puts at risk staff positions at Ibis if additional funds to cover staff time cannot be secured or other projects are not available to cover that time. Ibis has also had to pause the next phase of the research project, hindering collection of crucial data on SRH experiences and preferences from under-studied populations that independent expert NIH reviewers deemed urgently needed.

18. On April 16, 2025, I filed a letter of appeal to the NIH on behalf of Ibis, appealing the termination of R01HD109320. In the appeal, I challenged the grant termination on the basis that the termination letter received was generic, false, and not based on the merit of the science or progress of the research project in question. I am appealing the termination, but I do not know whether it is possible to or how to recharacterize my project in my appeal to fit within any new agency priorities because I do not understand the terms describing the reasons for termination or even what the new priorities are. I also do not know whether the appeal has any chance of success, given the language of the termination notice that the premise of my grant is incompatible with agency priorities.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 24th day of April, 2025.



Kelly Blanchard

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF NEAL SWEENEY ON BEHALF OF UAW

I, Neal Sweeney, pursuant to 28 U.S.C. § 1746, declare as follows:

1. My name is Neal Sweeney. My job title is Organizer, UAW Higher Education Department. My job duties include working closely with UAW local unions and UAW regions to develop strategic organizing goals and bargaining priorities to build power within the higher education sector; increasing membership engagement and mobilization through democratic, worker-led programs; supporting broad, diverse leadership development; and identifying and developing political and community action plans.

2. The International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) is one of the largest and most diverse unions in North America, with members in the United States, Canada and Puerto Rico and in virtually every sector of the economy including approximately 120,000 workers in higher education – graduate students, postdoctoral scholars, researchers, university staff, and faculty – at institutions across the country. From UAW's earliest days, it has been a leader in the struggle to secure economic and social justice for all people. UAW has a strong history of supporting and bargaining for contract provisions that ensure diversity, equity and inclusion in the higher education sector and in all workplaces. UAW has been actively involved in every workers' rights and civil rights legislative battle since the 1930s, including the campaigns to pass the Civil Rights Act of 1964, the Voting Rights Act of 1965, the Fair Housing Act, the Civil Rights Restoration Act of 1988 and legislation to prohibit discrimination against women, the elderly and people

with disabilities. In addition, UAW has long advocated for increased federal funding for scientific research, recognizing its importance for innovation, economic growth, and public health.

3. The UAW International Executive Board (which includes the President, Secretary-Treasurer, three Vice Presidents and nine Regional Directors) is responsible for carrying out the programs and policies approved by the Constitutional Convention delegates and running the day-to-day operations of the International Union. The UAW President's Office includes a number of departments that support UAW members, including the Higher Education Department. UAW members belong to more than 600 local unions across the U.S., Canada and Puerto Rico. Local unions get support in organizing new members, bargaining contracts, handling problems with employers, member education, political action, community activities and more from both the national UAW offices and centers and each of the nine regional offices.

4. This lawsuit uses the labels "UAW Member" and "UAW Pre-Member" to identify UAW represented workers. The term "UAW Member" refers to a worker who is covered by a collective bargaining contract and who pays dues in an amount determined by their pay structure and whether they have a legal right to strike. Dues are set by UAW Constitutional Convention delegates. "UAW Pre-member" refers to a worker represented by the UAW in initial contract negotiations who is not yet covered by a contract. These workers intend to become dues-paying members as soon as their unit reaches a collective bargaining agreement.

5. Approximately 75,000 UAW-represented workers depend on funding from the National Institutes of Health ("NIH") for their jobs including salary, benefits, research costs including supplies and reagents, travel to academic conferences, and training and mentoring opportunities.

6. The following UAW-represented positions rely on NIH grants for financial support: Research Assistant, Graduate Research Assistant, Graduate Assistant, Research Associate, Student Assistant, Fellow, Research Fellow, Clinical Fellow, Graduate Student Researcher, Graduate Student Researcher - Fellow, Graduate Student Researcher - Trainee, Project Assistant, Prestigious Graduate Fellow, Postdoctoral Scholar, Postdoctoral Fellow, Postdoctoral Research Fellow, Postdoctoral Scholar Research Associate, Postdoctoral Scholar Fellowship Trainee, Postdoctoral Research Scientist, Postdoctoral Research Scholar, Associate Research Scientist, Associate Research Scholar, Research Scientist/Engineer, Project Scientist, Specialist, Professional Researcher, and Coordinator of Public Programs.

7. The following institutions employ UAW-represented workers who rely on NIH funding to support their jobs: University of Alaska, University of Washington, Washington State University, Western Washington University, University of California, California State University, California Institute of Technology, Pardee Rand Graduate School, University of Southern California, Saint Louis University, Princeton University, University of Pennsylvania, Pennsylvania State University, University of Maine, University of New Hampshire, University of Vermont, Northeastern University, Worcester Polytech Institute, University of Massachusetts, Harvard University, New York University, Columbia University, University of Connecticut, Albert Einstein School of Medicine, Rockefeller University, Weill Cornell Graduate School of Medical Sciences, Icahn School of Medicine at Mt. Sinai, as well as NIH Fellows who are part of the NIH Intramural Research Program.

8. The following UAW Locals represent NIH-funded workers: UAW Local 1907 (University of Alaska), UAW Local 4121 (University of Washington), UAW Local 4591 (Washington State University), UAW Local 4929 (Western Washington University),UAW 4811 (University of California), UAW 4123 (California State University), UAW Local 2478 (California Institute of Technology), UAW Local 872 (University of Southern California), UAW Local 2322 (University of Massachusetts and Worcester Polytech Institute, UAW Local 5118 (Harvard University), UAW Local 2110 (New York University), UAW Local 2710 (Columbia University), UAW Local 4100 (Columbia University and Icahn School of Medicine at Mt. Sinai), UAW Local 6950 (University of Connecticut), and UAW Local 2750 (NIH Fellows). For initial contract negotiations, workers are represented by the UAW International and are assigned to a local union by the International Executive Board following ratification of the first collective bargaining agreement.

9. Since late January 2025, UAW has witnessed mounting disruptions in NIH-funded research across the campuses where our members work. UAW local unions and the International Union have fielded an increasing volume of inquiries and grievances regarding employers attempting to prematurely end term positions via layoffs, lack of notice for layoffs, and other abrupt changes to work assignments and funding.

10. Our members are at the front lines of American biomedical research—developing therapies, conducting basic science, and contributing to public health advancement. Yet their careers are being destabilized by bureaucratic inaction and unexplained political interference. UAW members have many concerns including:

a. *Job Insecurity and Interrupted Appointments*: We have received widespread reports that members' employment terms have been shortened and renewal decisions delayed, or start dates rescinded because of uncertainty surrounding cancellations or threatened cancellations of NIH funding. Postdocs, research staff, and graduate student researchers in particular have been told by principal investigators (PIs) that they cannot be reappointed unless or until NIH makes funding determinations that are months overdue. For example, at one institution, University of California, since March 5, 2025, we have received 17 layoff notices, 2 reductions-in-time, and 6 non-renewals of contracts due to NIH funding cuts and delays. These numbers are sure to increase as the number of cancelled grants increases, and due to further delays in both the issuance of new awards and renewal of existing awards. Some of the impacted members are on F-1, H-1B or J-1 visas and could be at risk of deportation if their positions are ended.

b. *Disruption of Research and Academic Progress and Missed Career Milestones*: Many of our members report being unable to complete their experiments or thesis research. Some have had to abandon critical data collection due to the unavailability of lab resources. NIH grant uncertainty has caused members to pause ongoing projects, re-scope dissertation topics, and in some cases, consider leaving their programs entirely. Many institutions have frozen hiring including the University of California, Harvard University, University of Washington, Washington State University, Columbia University, and the University of Pennsylvania. As many of our members are on term positions and are rehired or reappointed on a periodic basis, a hiring freeze could result in them losing their jobs. For example, at University of California San Francisco, a grant to study infectious diseases was suddenly cancelled leaving hundreds of researchers without funding to complete a multi-year study. Across institutions, members planned to apply for K99 or other independent NIH awards this spring but were advised by faculty to delay applications until NIH resumes normal operations. We are aware of members who have withdrawn from job searches, declined postdoctoral offers, or may need to delay graduation due to NIH-related instability. In addition, we are aware of members who are seriously exploring opportunities outside the United States as a result. In another example, over 200 researchers are being impacted by the cancellation of a single grant at one University of California campus, including postdoctoral researchers in infectious

diseases who were told by their PI that their appointment could be ended in as soon as 30 days.

c. *Irreparable Harm.* The loss of stability, research continuity, and training momentum is already having lasting effects. Even if NIH resumes normal grant processing and ceases terminating grants tomorrow, the damage done to our members' careers, experiments, immigration status, and trust in the research enterprise is irreversible. The delays are already chilling career interest in graduate education and postdoctoral research, which threatens to create downstream shortages of qualified biomedical researchers and faculty. In addition, the harms fall disproportionately on international scholars, first-generation college graduates, and members of underrepresented communities who cannot weather prolonged uncertainty or self-fund their research careers. Many of the affected members are first-generation scholars or from historically marginalized groups, including those working on NIH-funded disparities research. These disruptions will have a disproportionate effect on efforts to diversify the biomedical research workforce.

11. The following are among the types of NIH grants on which UAW-represented workers rely that that have either been cancelled or threated with cancellation: Individual Fellowships to promote diversity including F31, F32, D-SPAN; Training grants including T32; Career development awards including MOSAIC K99/R00, K12 and Institutional Research and Academic Career Development Awards (IRACDA); Science Education Partnership Award (SEPA); Post-baccalaureate Research Education Program (PREP); R-series grants including Diversity Supplements to NIH R01 awards, Initiative for Maximizing Student Development (IMSD) R25, and other R-series grants; Maximizing Access to Research Careers (MARC) Program; and Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern.

12. Below are examples of the research done by UAW members that has been impacted by NIH's grant cuts:

a. Studies on cancer biology including how cells respond to DNA damage;
b. Studies on how to better treat traumatic brain injuries, which disproportionately impact combat veterans;
c. Research exploring muscle regeneration following traumatic muscle injuries;
d. Studies on the toxicity of pollutants in the atmosphere including nanoplastics;
e. Research on cognitive health and chronic disease in older adults;

f. Studies aiming to understand brain developmental disorders;

g. Research on new treatments for chronic pain and substance use; and

h. Studies on mitigating bone loss during cancer treatments.

13. I have seen or heard about more than 100 grant cancellation notices received by UAW members. An example of the language used in such notices is: "I am writing to let you know that due to changes in NIH/HHS priorities, the maximizing opportunity for scientific and academic independent careers (MOSAIC) program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grant policy statement. Further awards will not be made, and NIGMS will not permit no cost extensions."

14. Many of the UAW members who have received these cancellation notices received the same generic explanation—that the grant or fellowship was being cancelled due to "changes in NIH/HHS priorities."

15. UAW is a plaintiff in this lawsuit to protect UAW-represented workers' terms & conditions of employment insofar as NIH directly funds UAW member jobs and the loss or threatened loss of funding jeopardizes UAW members' jobs, as well as training opportunities NIH would have funded. In addition, UAW has a long-standing history of supporting increased federal funding for scientific research, recognizing its importance for innovation, economic growth, and public health.

16. Given the public statements made by members of the Trump Administration and targeting of individuals who participated in past legal efforts, UAW members have expressed fears that participating publicly in this lawsuit could jeopardize their future eligibility for federal research funding. As many of our members are early career scientists, access to such federal funding is essential to their long-term academic and research goals, and losing these opportunities would significantly disrupt their career trajectories. In addition, given the current political climate surrounding diversity, equity and inclusion efforts, many have expressed to me that public participation could negatively affect how they are perceived by colleagues, both at their institutions and in the broader field where they work, and thereby impact future job opportunities, and by the public at large.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 20th day of April, 2025.

Neal Sweeney

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, et al., *Plaintiffs,* v. NATIONAL INSTITUES OF HEALTH, et al., *Defendants.*	Case No. 1:25-cv-10787-BEM

DECLARATION OF JEREMY M. BERG, PH.D.

I, Jeremy M. Berg, declare as follows:

Background

1. I am a former director of the National Institute of General Medical Sciences (NIGMS), one of the twenty-seven National Institutes of Health (NIH). I served as director of NIGMS from 2003 to 2011. The purpose of NIGMS is to support research and training of scientists across a wide range of areas, including biochemistry, cell biology, genetics, computational biology, bioinformatics, anesthesiology, wound healing, and burn and trauma research. The United States' ability to effectively treat, diagnose, manage, and ultimately cure diseases requires an understanding of their underlying mechanisms and biology. NIGMS' investments in fundamental basic research have supported 90 Nobel prizes and improvements in treatments for diseases including heart disease, cancer, neurological diseases associated with aging, sepsis, and many others.

2. NIGMS was organized into four programmatic divisions and a center: Cell Biology and Biophysics; Genetics and Developmental Biology; Pharmacology, Physiology and Biological

Chemistry, Minority Opportunities in Research, and the Center for Computational Biology. In addition, it has a Grant Management Office, an Office for Scientific Review, an Evaluation Office, an Office of Extramural Activities, an Office of Communications, a Budget Office, and the Office of the Director. There was also a training committee that consisted of POs from the various scientific divisions who oversaw the different institutional programs.

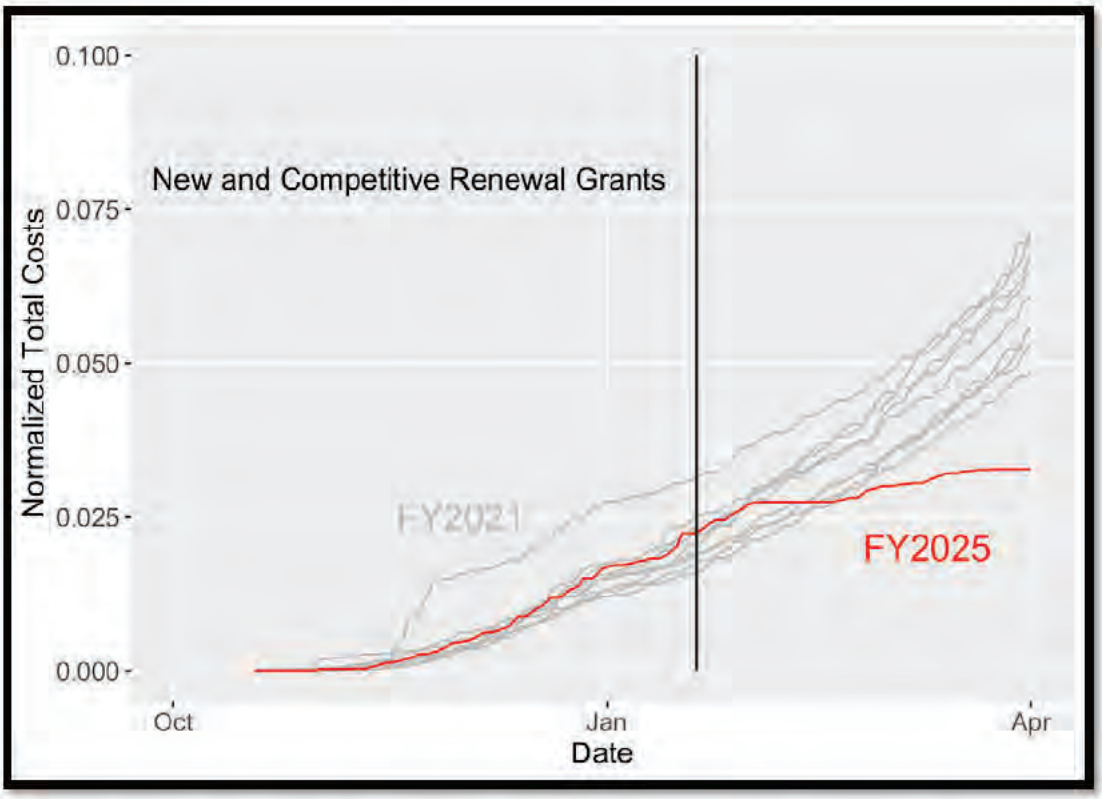
3. My responsibilities as director of NIGMS included staying information about, planning and participating in, and, in some cases, leading activities across the NIH. The ICs directors met together with the NIH director and other leaders typically monthly.

4. I left NIH in 2011 to come to the University of Pittsburgh with my wife, a leading breast cancer screening expert who was recruited to this institution. Here, I have continued to conduct some NIH-funded research in the area of computational biology and also have helped to manage a range of programs that receive NIH funding.

5. Since January 20, 2025, delays and terminations in NIH funding have dramatically disrupted the work of advancing biomedical research and training the next generation of scientists. Steps that have contributed to these disruptions have included the "pausing" of grant-making processes at NIH, the extremely slow release of continuing awards for multi-year grants, the disruption of the regularly scheduled national Advisory Committee meetings required to approve grant applications prior to funding, the disruption of the peer review "study section" meetings required for grant application evaluation and prioritization, and other steps. More recently, these have included direct terminations of specific grants based not on lack of performance or any other irregularities, but claims that the aims of these grants no longer aligned with NIH's priorities.

6. Based on my personal analysis of publicly available data (through the NIH Reporter website), over $3.3 billion of NIH funding that would typically have been disbursed through NIH's

grant making and grants management process by this point in the year has not been. The funding of new and competitive renewal (covering the continuation of projects that are nonetheless fully peer reviewed) grants is strikingly different starting shortly after January 20, 2025, compared to the preceding decade. In the image, below, the relatively flat line (red) for fiscal year 2025, after the first week of the current Trump administration reveals behavior that is completely distinct from that in previous years.



7. Through April 7th, more than $1.6 billion is missing from the funding that would be anticipated from continuation awards for multi-year grants. In addition, more than $500 million is missing in new grant funding from grant applications that undergo the highly competitive scientific peer review, based on comparison with the level of new grants awards from this same period from previous fiscal years.

8. If these estimates were broken down on a week-to-week basis (i.e., weeks in 2024 compared to weeks in 2025), the estimated difference is stark. In Weeks 4-11 of 2024 (i.e., January 20, 2024, through March 14, 2024), NIH awarded a total of $4.08 billion with 8,071 awards. For comparison, in Weeks 4-11 of 2025 (i.e., January 20, 2025 through March 14, 2025), NIH awarded a total of $2.45 billion with 4,961 awards. This represents a reduction of approximately 40%.

9. Narrowing the focus to new awards (and competitive renewal awards) that require study section and advisory council review prior to the award, in those same weeks, NIH awarded $740 million in 1,756 awards in 2024 but only $360 million in 781 awards in 2025. Focusing further still just on Weeks 6-11 (February 3rd to March 14th), the comparison is even more striking: 1,342 awards for $576 million in 2024, compared with 395 awards for $180 million in 2025, a reduction of approximately 69%.

10. In a recent analysis, which includes awards with April 1st budget start dates, the estimated difference for Weeks 12-13 (i.e., the period from March 14, 2025 to April 1, 2025) is $1.04 billion. Of this, $780 million is due to non-competitive renewal awards that were anticipatable during this period—since many grants were due for renewal by April 1, 2025. In addition, based on the new and competitive renewal awards made during this same period in 2023 and 2024, I estimate that there is a $260 million reduction in anticipatable new and competitive renewal awards in 2025.

11. Similarly, scientific colleagues have received grant terminations that have completely upended the work of their research labs, staff, and students. For example, all the awards for the Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Potential have apparently been terminated. This program is intended to do preparatory work for viruses and other pathogens that might cause pandemics in the future; and again went through a competitive award

process. These awards were terminated on the grounds that the COVID pandemic is over and, therefore, this research is no longer needed. It is hard for me to understand the logic of the termination of these forward-looking looking grants when the risk of a pandemic from COVID and other viruses persist.

12. As further described below, these disruptions and terminations are completely contrary to my previous experience both at and with the National Institutes of Health.

Role of NIH in Biomedical Research at Universities

13. Since the 1930s, the NIH and its predecessor agencies have supported the advancement of the United States' understanding of human disease and disability by funding training and research. In 1944, Congress formally created the NIH as part of the Public Health Service in order to encourage scientific institutions, other public institutions, and scientists in the conduct of research and demonstrations related to the causes, diagnosis, treatment, control, and prevention of physical and mental illnesses and disability. Congress specifically authorized support of research through grants to universities, hospitals, laboratories, and other public or private institutions for research projects after review by the NIH institutes' national advisory councils. Similarly, Congressional funding for training and fellowships dates back more than 50 years.

14. Since the 1930s, Congress has also added new institutes and centers focusing on different diseases, organ systems, life stages, or other aspects of biomedical research. For example, Congress specifically created NIGMS in 1962 to cover biomedical research of interest to two or more existing institutes or that are not covered by other institutes. Today, there are 27 institutes and centers as well as the Office of the Director within NIH. With the exceptions of the Center(s) for Scientific Review, the Center for Information Technology, and the NIH Clinical Center, the

individual institutions, centers and the Director have the authority to issue grants to researchers through their organizations.

15. Today, Congress appropriates more than $47 billion to the NIH's institutes and centers to advance biomedical research, including through grants to extramural researchers and institutions. Over 85 percent of NIH's annual funding to advance biomedical research powers the more than 38,000 principal researchers, research projects, and trainees in external organizations across the United States. This funding may cover everything from a principal investigator or junior researchers' salaries and benefits to research supplies, as well as real research costs that are not readily attributed to specific projects, often referred to as indirect costs.

16. NIH grants are typically awarded for an average of four years because the advancement of biomedical research benefits significantly from stable funding across a number of years. Very few research projects of any scientific significance can be completed in less than two years. Generally, grants are not fully funded all at once. An initial award in one fiscal year is followed by continuation (or non-competitive renewal) awards in subsequent years pending submission of an acceptable scientific and financial progress report. Thus, at any given point in time, about 80 percent of NIH's external funding is committed to existing research, support for the NIH intramural research program, or other costs such as NIH operations. The remaining 15 percent is available for new grant applications and the competitive renewal of long-term research projects. Stability is important to scientific investigation, particularly to encourage researchers to pursue innovation and risk in biomedical research. NIGMS has developed a variety of methods to provide stable funding for researchers so that productive or promising projects are not interrupted.

17. The stability of these grants also furthers the building of research capacity and the training of both graduate students and early-career scientists. A large proportion of pre- and

postdoctoral scientists are supported during some or all of their training periods via research project grants rather than training awards. This situation exists because many members of research teams funded by NIH research project grants include graduate students and postdoctoral researchers who engage in research as a key component of their training activities.

18. Through the Ruth L. Kirschstein National Research Service Awards and other programs, Congress has historically directed funding to public and private institutions specifically for the pre-doctoral and post-doctoral training of individuals to undertake biomedical research. Since 1972, such funding has included explicit provisions directed toward increasing the percentage of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) into fields of biomedical research. This is particularly important since project selection and other aspects of research related to health can depend on the life experiences of those engaging in research.

19. Institutional training grants (T32s) can be used to cover the costs of predoctoral or postdoctoral students. Individual grants, typically classified as F-series ("Fellowship") or K-series ("Career Development") grants can be used to provide stipends to researchers at all stages of their career, cover tuition and costs, and fund other expenses.

20. At the direction of Congress, NIH and institutes like NIGMS have also increased their funding in specific research areas. For example, this is true for research related to HIV/AIDS which has been coordinated through the NIH Office of AIDS Research. When I was a department chair at Johns Hopkins School of Medicine in the 1990s, there were serious discussions about where non-AIDS patients were going to be treated as beds at Johns Hopkins Hospital filled with AIDS patients. But with the support of NIH, the United States developed an understanding of basic biochemistry and virology of the HIV virus, identified a variety of drug targets and, subsequently,

developed drugs that have turned HIV infection from a death sentence into a treatable chronic condition. For some patients, the newest research has achieved a true cure to their HIV infection. Considering continued outbreaks and deaths from HIV/AIDS, the potential to reduce this public health risk in vulnerable communities and internationally is profoundly important.

NIH Funding Priorities Based on Congressional Direction & Scientific Assessment

21. In addition to Congressionally directed funding, the Director of the NIH and each institute and center engages with its advisory council, policy makers, scientific and professional societies, and other public stakeholders to identify agency funding priorities. Congress has directed the NIH to assemble accurate data to assess research priorities including information to evaluate scientific opportunities and public health disease burdens, including progress in reducing health disparities. NIH publicizes the data on the study populations of clinical research funding by its institutes and centers on its website. NIH also considers disease burden in the United States and the potential for return on investment to the United States; rare diseases and conditions; and the biological, social, and other determinants of health contribution to health disparities in identifying research priorities. These priorities are reported to Congress and publicized on its website via the NIH strategic plan.

22. At NIGMS, the institute specifically engaged in scientifically based strategic planning on a five-year basis. While I was NIGMS director, we developed the first formal NIGMS strategic plan, NIGMS Strategic Plan 2008-2012: Investing in the Future.[1] This plan was developed through extensive interactions with stakeholders from different communities around the country and staff across NIGMS and NIH.

[1] NAT'L INST. GEN. MEDICAL SCIENCES, INVESTING IN DISCOVERY (2007), https://www.nigms.nih.gov/sites/nigms/files/migrated/NIGMS-strategic-plan-2008-2012.pdf

23. We also developed a strategic plan specific for research training.[2] The four themes of this plan are Theme I: Research training is a responsibility shared by NIH, academic institutions, faculty and trainees; Theme II: Research training focuses on student development, not simply selection of talent; Theme III: Breadth and flexibility enable research training to keep pace with the opportunities and demands of contemporary science and provide the foundation for a scientific career paths; and Theme IV: Diversity is an indispensable component of research training excellence, and it must be advanced across the entire research enterprise.

24. Once agency priorities have been identified, each institute and center issues notices of funding opportunities (NOFOs) for specific grant mechanisms, some of which are targeted to specific areas and some are open-ended invitations to investigators to propose problems of interest and specific approaches that fall within the given NIH institute or center's mission.

25. As further described below, when reviewing applications for NIH funding, both the institute and its advisory council explicitly consider whether an application is consistent with its mission and scientific priorities identified in its strategic plan.

Review of External Funding at NIH Based on Scientific Merit and Strategic Plan

26. The NIH receives approximately 50,000 grant applications per year. NIGMS alone awards and manages more than 4,500 grants on average and reviews nearly 1,000 grant applications (in addition to those reviewed by study sections at the NIH's Center for Scientific Review) received in response to NOFOs. As part of the NIH mission to advance biomedical research, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

[2] https://www.nigms.nih.gov/sites/nigms/files/migrated/NIGMS-Strategic-Training-Plan.pdf

27. Notices of funding opportunities explicitly incorporate the criteria used to assess scientific and technical merit of each grant application. Criteria can include the scientific significance of the proposed project, including the strength of the scientific premises of the grant; the investigators' expertise and resources; the potential innovative impact of the proposed research; and whether there is a rigorous and feasible approach to address the aims of the project. Other criteria include justification of the proposed budget and duration in relation to the proposed research. For clinical research, patients need to be protected from research risks including the risk of needing to stop the research and the application also needs to address the appropriateness of the proposed study population.

28. When a scientist submits a grant application through their organization, the NIH assigns the application to a study section at the Center for Scientific Review for peer review or to study sections at a specific NIH institute or center for more scientifically specialized topics. Study sections are composed of 20-30 independent researchers from the scientific community who have the expertise to assess topics such as Basic Mechanisms of Diabetes and Metabolism or Chemical Biology and Probes. There are approximately 250 standing study sections that meet at least three times a year on specified topics. Special emphasis panels or study sections also meet to review applications for more specialized programs or for projects that fall outside an existing study section.

29. The study section meets, reviews, and scores an application for scientific and technical merit. The review is time intensive and done on a mostly voluntary basis. Each reviewer on a study section is assigned between 4-10 applications. Each application has two primary reviewers and an additional reader who present the application for discussion at one-to-two-day meetings. Scores can significantly shift as key features or flaws are noted. Scores from different

study sections are normalized so that scores from different study sections can be compared. Fewer than half of applications make it through this part of the process with a significant chance of being selected for funding.

30. I served as a study section member and study section chair just prior to my appointment as NIGMS director. For applications for which one had primary responsibility, each reviewer writes a critique and assigned numerical scores. I found that I spent approximately five hours per application reading and writing these critiques. This is in addition to one's normal job and personal responsibilities. At study section meetings, each application is presented and discussed. Each application is presented by two primary reviewers, briefly describing the subject of the proposal and the approach and outlining major strengths and weaknesses. An additional reader provides further comments, and the application is discussed by the study section committee. After the discussion, the primary reviewers give their final numerical scores, and each member of the study section provides a score in secret although members are encouraged to announce if they are voting outside of the range of the primary reviewers as an indication that they are weighing their own judgements or certain arguments by the primary reviewers strongly.

31. Advisory councils from each institute or center then meet and review the grant critiques (called summary statements) with NIH staff to ensure that the first level of peer review appears to have proceeded appropriately and to assess alignment of the application with the institutes' funding priorities. Advisory councils are committees of 10-12 academic scientists and other experts (e.g., patient advocates, economists) who typically serve four-year terms and are appointed by the Secretary of Health and Human Services. Advisory councils provide oversight of the first stage of peer review and make recommendations about applications that should be given higher or lower priority given the state of science in a given institute or center's field, and the

mission and extant portfolio of said institute. Advisory councils typically meet three times a year with meetings scheduled years in advance. These meetings align with the normal funding cycles for grant review process.

32. Finally, each institute and center's director make funding decisions with the advice of program officers and senior leaders in the institute or center. Funding decisions are largely based on peer review scores, but also with consideration regarding the existing grant portfolio, a center's publicized priorities, or recommendations of staff. Budgets are adjusted based on peer review, staff recommendations, and the availability of Congressionally appropriated funds. Grants are then awarded to each researcher's institution. Successful applicants receive Notices of Award ("NOAs"). The NOA identifies the institutional grantee, one or more principal investigators, and specifies the amount of the award, its duration, and all other terms and conditions with which the grantee must comply.

33. Before this year, I have never observed nearly all study sections and advisory councils canceled for a funding cycle. On January 21, the Acting Secretary of Health and Human Services informed NIH that all notices in the Federal Register would need to be approved by a Presidential appointee. This is important because study sections and advisory councils are committees subject to the Federal Advisory Committee Act (FACA), a transparency statute enacted in 1972. My understanding is that this law was intended to prevent the federal government from receiving advice in secret. Here, it was being used to block normal grant-making processes. Approval of grant applications and peer review is required in order for an application to be eligible for funding.

34. NIH application submission, study section review, advisory council consideration, and funding decision and notice of award generation normally occur on a regular schedule with

three cycles per year.[3] In my experience, institutions and investigators are quite familiar with and anticipate these scheduled dates. Many investigators know upcoming application due dates off the top of their heads and upcoming advisory council meetings dates are selected and publicized in institute web pages a year or more in advance.

Review and Award Cycles

	Cycle I	Cycle II	Cycle III
Application Due Dates	January 25 - May 7	May 25 - September 7	September 25 - January 7
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

Continued Funding at NIH Based on Scientific Merit & Performance

35. NIH staff, such as grant management officers and scientific review officers, are also assigned to manage the more than 59,000 grants that NIH manages in a year. In 2023, these grants supported 38,000 principal investigators and more than 300,000 researchers at more than 2,500 institutions across the country.

36. Due to the nature of funding scientifically significant but innovative and sometimes risky nature of biomedical research, investigators have the flexibility to adjust their research efforts depending on ongoing discoveries or other developments in the scientific field. But the NIH's staff still review annual progress reports to assess whether or not the researcher has continued to make progress on the project appropriate for what was in their grant application.

[3] https://grants.nih.gov/grants-process/submit/submission-policies/standard-due-dates.

37. NIH program officers and grants management specialists must review these reports and approve a new year of funding through an administrative review without the involvement of study sections and advisory councils. As mentioned above, due to the importance of funding stability in advancing scientific investigation—absent scientific misconduct or other significant events—these funding streams are almost always approved in a timely manner as grants come up for review based on their start date.

Rarity of Grant Terminations

38. The NIH rarely terminates grants. I do not recall any instances of such terminations by NIGMS during my nearly eight years as director. Prior to 2025, I am only aware of two such terminations in subsequent years. One involved an aging investigator who was not longer able to conduct the research (and who died shortly thereafter) and another involved an investigator who separated from his university following investigations into sexual harassment involving younger scientists.[4]

39. Otherwise, in instance of concerns about performance of the grant, rather than terminating a grant, the NIH has generally discussed with the grantee or with others at the grantee organization to pursue corrective action prior to making any additional awards.

40. Finally, in instances of scientific misconduct, the NIH still seeks to preserve the results of the research if possible. Scientific misconduct includes, but is not limited to, fabrication of the data and results from a scientific study or plagiarism of another person's processes and results without giving appropriate credit.[5] Under many circumstances, misconduct investigations,

[4] *See* Amy Harmon, *Chicago Professor Resigns Amid Sexual Misconduct Investigation*, N.Y.TIMES (Feb. 2, 2016), https://www.nytimes.com/2016/02/03/us/chicago-professor-resigns-amid-sexual-misconduct-investigation.html

[5] Office Res. Integrity, *Definition of Research Misconduct*, DEP'T HEALTH & HUMAN SERVS., https://ori.hhs.gov/definition-research-misconduct (last visited on Apr. 2, 2025).

conducted by the grantee organization or their designee, identify problematic scientific publications and push for correction or retractions for impacted publications. But in other instances, publications are cleared by the investigation with no evidence of influence on the publication due to the inappropriate behavior.

41. This stands in sharp contrast to what is occurring during the present administration. Large number of grants are being terminated, allegedly because the award "no longer effectuates the program goals or agency priorities" or for other reasons. Some many grants are being terminated that NIH has added a field to the NIH Reporter database to designate terminated grants. This did not exist prior to April 2025. The Department of Health and Human Services (HHS) now posts a link to a spreadsheet of terminated grants on its TAGGS database landing page.[6]

42. I have been examining the terminated grants lists on a regular basis. For the week from April 11, 2025 through April 18, 2025 only a single new grant (a supplement to an existing grant) was added. However, data from NIH Reporter over the same period indicated that more than 20 awards were terminated over this period. This inconsistency adds further confusion about the nature of ongoing terminations.

43. NIH has recently also been making changes to its use of the Payment Management System (PMS). Universities do not receive payment when an NIH grant is awarded, but rather are given the ability to request reimbursement through the PMS. DOGE is apparently introducing additional steps in this process and NIH had, at least for a period, halted all payments through the PMS and, perhaps, was using this system to withhold grant payments to specific institutions.[7]

[6] https://taggs.hhs.gov/

[7] https://www.washingtonpost.com/politics/2025/04/17/doge-trump-grants-hhs-nih-backlog/

Funding Disruptions Devastating, Without Alternatives

44. In the long term, if these disruptions in Congressionally directed funding continue, the biomedical enterprise both in public and private institutions is in danger. As an example of how basic research helps to fuel rapid progress in developing new and safer treatments and prevention strategies, the U.S. Food & Drug Administration recently approved a first-in-class non-opioid medicine for mild to moderate pain (suzetrigine, brandname Journavx).[8] This was based on decades of basic and more applied research in NIH-funded academic and private-sector laboratories. The loss of any of the large amount of information or techniques generated from this research would have made approval of this pain medication impossible. Move over, many of the scientists involved— including those in industry—were trained at the NIH or in academic laboratories supported by the NIH. In the long run, these advancements have the potential both to provide a new alternative to treat post-surgical pain, but also to address the demand side of the opioid public health crisis.

45. There are not alternative sources to replace the NIH's more than $40 billion in biomedical research funding. In 2022, the NIH invested more than 25 more times on grants than the next largest funder, the Wellcome Trust based in the United Kingdom.[9] Combining then the next 25 largest funders of biomedical research would not replace the NIH's annual funding of biomedical research. Moreover, as private or non-US based funders, those funders are unlikely to have the same priorities identified by Congress and by US-based researchers and stakeholders.

[8] Press Release, FDA Approves Novel Non-Opioid Treatment for Moderate to Severe Acute Pain (Jan. 30, 2025), https://www.fda.gov/news-events/press-announcements/fda-approves-novel-non-opioid-treatment-moderate-severe-acute-pain

[9] Nisha Gaind, *How the NIH Dominates the World's Health Research*, 639 NATURE 554 (2025), doi: https://doi.org/10.1038/d41586-025-00754-4

Terminations Will Likely Cause Severe Career Disruption and Harm

46. Throughout my career, I have also helped guide scientists at the beginning of their independent careers as they sought to compete for NIH funding. Prior to coming to NIH, I was Director of the Department of Biophysics and Biophysical Chemistry at the Johns Hopkins University School of Medicine. In this role, I conducted research in partnerships with graduate students including combined MD/PhD students, and postdoctoral fellows with much of this work supported by NIGMS and other NIH institutes.

47. As a department chair, I recruited many faculty starting their independent careers. Obtaining NIH funding was an essential step in developing their careers, both in terms of providing funds for their research and for demonstrating that their ideas and research was sufficient good that it has passed the rigorous bars for NIH funding.

48. At my present institution, it is an unwritten rule that all faculty members need to hold two substantial NIH grants to receive tenure. Again, this reflects both the financial support for their continuing research and the recognition and prestige associated with competing through peer review and the rest of the NIH funding processes.

49. I have never had to deal with a faculty candidate who have had an NIH grant or grants terminated or withdrawn from consideration for reasons of "agency priorities." However, it is difficult for me to imagine such an individual competing for a coveted faculty position against a large pool of qualified candidates. This reflects the substantial likely irreversible personal harm done to individual scientists through this capricious use of NIH funding for political purposes.

50. As an undergraduate, graduate student, and postdoctoral fellow, my training and research were supported through research grants to my research mentors. When I started my independent career, my research projects were funded through a then-new program directed to

beginning faculty members. The continuity of Congress and the American people's investment in biomedical research via the NIH has been vital to my career path. The United States has similarly invested in the training and research of numerous students, early career scientists, and faculty in every state and territory. It is a shame that these interruptions in NIH funding now endanger the advancements and institutions powered by those individual researchers.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on this 24th day of April 2025, in Gibsonia, PA.

Jeremy M. Berg, Ph.D.
Former Director (2003-2011)
National Institute of General Medical Sciences
National Institutes of Health

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF SCOTT W. DELANEY, ScD JD MPH

I, Scott W. Delaney, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am offering this Declaration in my individual capacity and not on behalf of my employer.

2. I am an epidemiologist at the Harvard T.H. Chan School of Public Health (HSPH). My research investigates how environmental, social, and legal forces affect neurodegenerative diseases in older Americans and neurodevelopmental health in American children. I have conducted epidemiologic research at HSPH in various capacities—first as a student, then as a postdoctoral research fellow, and finally as an independent researcher—for 11 years. I hold a Doctor of Science from HSPH (ScD, 2020); a Master of Public Health from the Johns Hopkins Bloomberg School of Public Health (MPH, 2015); a Juris Doctor from the University of Illinois College of Law (JD, 2004); and a Bachelor of Science from the University of Illinois College of Business (BS, Finance, 2000). Prior to my career in epidemiology, I practiced law in several capacities.

3. Formally, I hold the title of Research Scientist at HSPH. Research Scientists at HSPH have full privileges to conduct independent research and apply for grant funding as Principal Investigators (PIs). Throughout my career in epidemiology, I have applied for and received multiple types of grants from NIH either individually or as part of teams. These include training grants (T90 and T32 as a student trainee), a fellowship grant (F31 as a student PI), multiple loan repayment awards ("L" grants as a PI), and multiple research "R" grants (as a Co-Investigator). Moreover, my current research activities are supported almost entirely by NIH research grants. Based on these experiences, I am exceedingly familiar with a broad spectrum of grant mechanisms available from NIH.

4. In early March 2025, I read news articles reporting that political appointees within the Department of Health and Human Services (HHS)—either at NIH or elsewhere—were directing NIH to terminate certain research grants. These news articles reported that NIH was specifically targeting grants addressing transgender issues or "diversity, equity, and inclusion" (DEI) topics, but those terms were never defined in the press. Importantly, news articles contained little detail on specific examples of terminated grants, and it was not publicly known how many grants had been terminated, which grants had been targeted for termination, or the exact reasons that the grants were being terminated beyond the nominal excuses noted above. This lack of government transparency raised challenges for the health science research community.

5. On March 7, 2025, I created an online spreadsheet using Google Sheets to track news reports of specific terminated NIH grants. The first version of the Google Sheet included three columns of information for each terminated NIH grant, including the grant's title and type (e.g., R01, etc.), and the NIH institute or center (IC) that had funded the grant. Because news reports were scarce, I also sought to crowd-source information on terminated grants. To that end, I

posted a message and link to the Google Sheet on Bluesky, a social media platform commonly used by academic researchers, asking the Bluesky community to add any information about terminated grants they knew about to the Google Sheet.

6. In the ensuing 1-2 weeks, I received multiple user-submitted entries of terminated grants, which I attempted to verify manually using data from NIH RePORTER, a searchable online database of NIH grants, and by emailing affected PIs. I also began tracking a larger number of characteristics about each terminated grant, and I expanded the number of internet sources I used to find evidence of terminated grants. In mid-March, the website for the HHS Tracking Accountability in Government Grants System (TAGGS), published for the first time a short PDF list of grants that NIH had terminated. The list, however, was both incomplete (i.e., it did not list all grants that had been terminated at that time) and somewhat inaccurate (i.e., it listed some grants twice and appeared to include a grant that had not yet been terminated).

7. As a result, I attempted to manually verify information in this HHS TAGGS PDF document to the greatest extent possible, and I used it to supplement information gleaned from news reports, user submissions, Doge.gov, and other internet sources. As the Google Sheet of terminated grants grew, I began to publicize it more broadly via emails to my professional network and through frequent posts about it on Bluesky. In response to these efforts, I received suggestions to meet with many other researchers who either had their grants terminated or were interested in the terminated grant tracking effort. One such researcher was Dr. Noam Ross of rOpenSci.

8. At the same time that I was building out the public-facing Google Sheet and crowd-sourcing information about terminated grants, Dr. Ross was engaged in an independent effort to scour federal databases, including NIH RePORTER, USASpending.gov, and the HHS TAGGS

system, for evidence of terminated grants. These systems track government accounting actions related to grants, including changes to government financial outlays (i.e., payments) for grants. Thus, for example, if Dr. Ross observed on USASpending.gov that the budget for a specific grant was prematurely changed to $0, he used that information as one piece of evidence that the grant may have been prematurely terminated. These federal databases, while technically public, are difficult to access and interpret. Dr. Ross' efforts to combine and organize evidence of grant terminations from these sources was highly complementary to my news- and crowd-sourced evidence. In mid-March, we met virtually and agreed to combine our efforts to form the current iteration of our terminated grant tracking platform. Thus, all counts of terminated grants set forth in this Declaration—as well as the underlying database of terminated grants that we have built together—result from our combined efforts.

9. Data in our database of terminated grants come from several sources. Among them are affected Principal Investigators (i.e., scientists), who we encourage to submit information on their terminated grants using a Google Form, which we have designed and published specifically for this purpose. We also aggregate data from news reports, social media, Doge.gov, USASpending.gov, NIH's X feed, NIH RePORTER, and the HHS TAGGS system. The HHS TAGGS system provides data in two ways. First, it details grant-based financial transactions with information that is updated at least daily. Second, TAGGS administrators periodically (~1/week) release a PDF list of terminated grants. The TAGGS PDF list is one source of information in our database among several. Because we aggregate from multiple sources, our database includes grants not yet listed on federal government websites, including the HHS TAGGS PDF of terminated grants, and we believe it is the most comprehensive, up-to-date resource currently available that quantifies and characterizes terminated grants.

10. To ensure each reader can objectively verify all details of our database, we list NIH-issued grant serial numbers, which are unique to each grant, website hyperlinks to federal databases describing each grant, and many other details for each terminated grant. These efforts to ensure transparency are critical for multiple reasons. Foremost is that the NIH grant termination process has been extraordinarily chaotic—far more so than is often reported in news articles. In many cases, the government has often provided incorrect and shifting information (knowingly or not) about exactly which grants were terminated, when, and why. Their estimates of the dollar value of grants terminated are even more unreliable. We also believe the government has restored a limited number of grants that it previously terminated, often without providing public notice. As a result, our database may contain a small number of minor inaccuracies. Nevertheless, based on my experience, I believe our dataset is the most accurate and most complete dataset of terminated grants currently available.

11. Our database includes extensive metadata on at least 28 different characteristics of each terminated grant. Among other characteristics, we track each grant's title, abstract (which succinctly describes the scientific background and aims of the grant), public health relevance statement (which is an NIH-required statement explaining in plain language how the grant will improve the public's health), and the grant's project terms (which describe the topics that relate to the grant's scientific aims). This enables us to characterize the health challenges and diagnoses each grant is meant to research. It also allows us to infer possible bases for each grant's termination.

12. Our database reveals that, on February 28, 2025, NIH began terminating hundreds of grants on topics that NIH is statutorily required to research. Specifically, as of Friday, April 18, 2025, at 11:00 p.m. EDT, we have identified 755 grants that NIH has terminated thus far based

on vague "policy" assertions. A true and correct list of these terminated grants is attached to this Declaration as Exhibit A. This number excludes grants that both (1) were terminated at Columbia University for alleged Title VI violations and (2) did not relate to topics otherwise targeted for termination. Importantly, this number almost surely underestimates the true number of terminations. While we often identify new terminations within 1 to 3 days of their effective date, it can take 10 to 14 days or more or us to learn of some new terminations. Thus, based on my experience tracking these grant terminations, I estimate there could be at least 100 more terminations than we currently count, and NIH continues to terminate new grants every week.

13. Terminated grants focus on a wide variety of health outcomes. These include projects on breast cancer, uterine cancer, anal cancer, stroke risk, cardiac health, Alzheimer's Disease, HIV prevention, suicide prevention, infertility, alcohol use disorder, smoking cessation, eating disorders, sexually transmitted infections, Covid-19, depression, psychopathology, pain, and many other conditions that very often disproportionately burden minority communities. Other terminated grants studied the harmful effects of health misinformation, discrimination, poverty, racism, loneliness, transphobic policies, and social stress, as well as the health-protective effects of social support, education, and school-based mental health interventions.

14. I also sought to quantify the financial impact of terminating these grants using grant-specific budgetary data from USASpending.gov, TAGGS, and NIH RePORTER. These systems report detailed information on financial budgets and outlays for all NIH grants, including the total budget allocated to each grant and the total outlay (i.e., money already transferred to recipients) for each grant. For example, grant R01ES035053 was a five-year grant to study reasons why Black women in the United States have higher rates of infertility than White women. The grant began in April 2023 and was scheduled to continue through January 2028.

USASpending.gov lists the total budget allocated for the full five years of this grant as $1,447,869.00. However, on March 27, 2025, NIH prematurely terminated this grant. USASpending.gov reports that, prior to termination, the government had paid out $649,351.22 on the grant, leaving $798,517.78 in unspent funds. We calculated the total financial impact of all grant terminations by aggregating these grant-specific budget numbers across all grants in our database.

15. The total budget originally allocated to the 755 grants in our database was approximately $3.0 billion. Most grants were terminated midstream after investigators had already launched their studies and spent a portion of the budgets they expected to receive. As a result, $1.4 billion has already been spent on projects stopped midstream, leaving the aggregate unspent value of these grants at $1.6 billion.

16. While NIH targeted a somewhat jumbled mix of grant *topics* for termination, it also targeted a spectrum of grant *types*. These types include project-based (i.e., research) grants, which support research on specific public health challenges that are set forth in the strategic plans of each IC. For example, the 2020-2025 strategic plan for the National Institute on Minority Health and Health Disparities (NIMHD) prioritizes research to "develop and test interventions to reduce health disparities." Consistent with this goal, NIMHD, through its director, issued Grant Number 5R01MD017509 for a 5-year intervention beginning May 14, 2022, to test whether directly reducing the income gap among older African American men in rural communities enhances their health and wellbeing. The grant was scheduled to last through January 2027. However, on March 14, 2025, half-way through the intervention, the grant was terminated. In another instance, NIMHD funded a proposed multi-year grant entitled, "Development of School-Based Prevention Intervention to Promote Adolescent Mental Health

Equity." The grant began on January 31, 2025, but was terminated just 40 days later on March 12, 2025. These grants exemplify a pattern, in which IC-specific directors awarded grants consistent with their IC-specific strategic plans, after which the grants were summarily terminated despite no change to IC-specific or overall NIH strategic plans.

17. In addition to research grants, NIH has also targeted training grants, which support the development of the next generation of health scientists. Training grants are key to meeting NIH's statutory obligations, and NIH Strategic Plan recognizes that the "strength of the NIH workforce depends on its sustainability and diversity." It observes that "[g]round-breaking, impactful biomedical and behavior research depends upon a diverse workforce, composed of people . . . from different backgrounds, who can provide a richness of perspectives necessary to inspire new ideas." NIH pursues this strategic goal with a mix of programs—some created directly by Congress, others by NIH—that support students and early career researchers at all stages of their training, from undergraduate studies through post-doctoral research.

18. For example, in 1974, Congress created the NIH National Research Service Award (NRSA) program to ensure "the availability of excellent scientists" in biomedical and behavioral research. This program was later renamed the Ruth L. Kirschstein National Research Service Award program, and its explicit aim today is "to ensure a diverse pool of highly trained scientists." To advance the aims of the NRSA program, NIH has created several grant mechanisms, which are designated with codes including F30, F31, F32, F33, F34, F35, T32, T34, T35, T90, TL1, and TL4. Some of these grants are run by institutions, while others are awarded to individual investigators. All NRSA grants, however, are awarded in service of Congress' command to support the training and development of a diverse corps of health science

researchers. Since February 28, 2025, NIH has terminated at least 139 NRSA grants with an aggregate budget of $153 million, of which $102 million was unspent prior to termination.

19. In addition to prematurely terminating large numbers of NRSA awards, NIH also changed the aim of them to remove any mention of recruiting diverse scientists. For example, among the most common types of NRSA grants are institutional T32 training grants. On November 15, 2024, NIH issued a new program announcement (PA-25-168) for the primary T32 grant mechanism, called the "Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32)." A true and correct copy of this program announcement is attached to this Declaration as Exhibit B. Like all eleven Parent T32 program announcements released during the past 25 years, PA-25-168 explicitly announced that the purpose of the NRSA program was to "help ensure that a *diverse* pool of highly trained scientists is available" for health science research.[1] PA-25-168 further noted that "individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply." And, critically, PA-25-168 (as it was originally issued) provided that reviewers of T32 applications should (1) consider the strength of the application's proposed "recruitment plan[s] to enhance diversity," and (2) "examine the strategies to be used in the recruitment of prospective candidates from underrepresented groups."

20. However, sometime after January 30, 2025, with no prior notice to potential applicants, NIH changed the language of PA-25-168 and added a banner to the top of the announcement reading "March 31, 2025 / This funding opportunity was updated to align with agency priorities." A true and correct copy of this program announcement is attached to this Declaration

[1] Parent T32 program announcements containing this language include PA-23-048, PA-20-142, PA-18-403, PA-16-152, PA-14-015, PA-11-184, PA-10-036, PA-08-226, PA-06-468, PA-02-109, PA-00-103.

as Exhibit C. Specifically, NIH removed all mention of diversity and all requirements to ensure the recruitment of diverse scientists. For example, the stated purpose of the program after the announcement was changed reads "to help ensure that a pool of highly trained scientists is available" for health science research, with the word "diverse" is conspicuously absent. The program announcement no longer encourages applicants from diverse backgrounds and, more importantly, no longer requires that reviewers of the applications evaluate the application's diversity-enhancing recruitment plans. Similar changes were made to other large NRSA program announcements, including the Parent F30, Parent F31, and Parent F32. In short, despite Congress' mandate to support scientists from diverse backgrounds, NIH scrubbed all requirements to ensure diversity from its most popular NRSA programs.

21. A separate example of terminated training grant programs from the Congressionally created NRSA initiative is the Minority Access to Research Careers program, which was first created in 1977. While the program's name has since changed to the Maximizing Access to Research Careers (MARC), its core goal has remained the same for 48 years, i.e., "to create and sustain inclusive [undergraduate] training environments for trainees from diverse backgrounds." Moreover, NIH has since created additional programs to augment MARC, most notably, the Undergraduate Research Training Initiative for Student Enhancement (U-RISE), which was launched in 2019. U-RISE explicitly aims "to develop a diverse pool of undergraduates" who plan to pursue higher education and careers in biomedical research. U-RISE and MARC effectuate the aims of the Congressionally created NRSA program by supporting mentorship, training, and other opportunities for diverse students at domestic universities, i.e., universities develop, apply for, receive, and administer both MARC and U-RISE grants.

22. For nearly 50 years, these programs have operated to diversify the biomedical workforce, supporting thousands of students from underrepresented backgrounds during that time. In 2024, NIH supported 63 U-RISE and 34 MARC programs. In the course of updating our database of terminated grants, I learned from press reports and personal communications that, on March 27, 2025, NIH issued stop work orders for all or nearly all U-RISE grants as well as many MARC grants. Moreover, the project end dates for many of these U-RISE grants has since been changed in federal databases to March 31, 2025, suggesting the entire nearly-50 year old program has been permanently terminated.

23. Other NIH programs aim to diversify the workforce at later stages of training. For example, through the congressionally required "Next Generation Researchers Initiative," the NIH aims to achieve sustainability by "enhanc[ing] opportunities for early-stage researchers by prioritizing funding of independent research applications" of early-stage researchers "such as policies to ... enhance workforce diversity." One approach to diversifying the workforce is called the Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (F31 Diversity), which supports promising graduate students in their final years of dissertation research. Another approach is NIH's Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) program, which facilitates the transition of promising postdoctoral researchers from diverse backgrounds, including those from underrepresented groups, to academic faculty positions at institutions throughout the country. These grant mechanisms fund a wide spectrum of research projects, from bench science to qualitative studies, such that the majority of the research they fund is unrelated to transgender health or DEI issues. Yet, in the past four weeks, NIH has terminated 19 F31 Diversity awards. Because many of these grants were on topics wholly unrelated to DEI issues, they were targeted based on the status of

the principal investigator's status as an underrepresented minority scientist. Moreover, all F31 Diversity and MOSAIC grant opportunities have disappeared from NIH's website.

24. Still another program to secure a diverse workforce of health scientists is the "Faculty Institutional Recruitment for Sustainable Transformation (FIRST) initiative," which aims to transform culture at NIH-funded institutions through the recruitment of faculty cohorts who have a demonstrated commitment to "diversity and inclusive excellence". On December 8, 2020, NIH issued RFA-RM-20-022, which was a call for grants entitled "NIH Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program: FIRST Cohort (U54 Clinical Trial Option)." This call was reissued twice in subsequent years as RFA-RM-21-025 and RFA-RM-22-008. In 2024, the FIRST initiative funded programs at 15 different universities. All 15 have since been terminated prematurely: 1 was terminated on March 12, 2025; 2 were terminated on March 21, 2025; and 12 were terminated on April 8, 2025. Combined, these programs comprised a $163 million investment on behalf of NIH in workforce development. Yet, NIH terminated each of these programs midstream, rescinding $106 million in funds these programs expected to spend over the next two-to-three years.

25. Beyond the termination of NRSA grants and cuts to the MARC, U-RISE, MOSAIC, and FIRST programs, I have learned through personal communications with affected Principal Investigators as well as press reports that NIH may also have terminated the Initiative for Maximizing Student Development (IMSD), the Institutional Research and Academic Career Development Awards (IRACDA), and the Postbaccalaureate Research Education Programs (PREP), which also supported the training of diverse researchers. Taken together, these widespread terminations of training grants—in addition to the terminations of many research

grants described above—comprise an abrupt and unprecedented reversal of support for health science research in the United States.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 19 day of April, 2025.

SCOTT W. DELANEY

EXHIBIT A

Award Number	Project Title	Awardee Organization	Termination Date
DP2AI164315	One Ballroom: Understanding Intersectional Stigma to Optimize the HIV Prevention Continuum among Vulnerable Populations in the United States	University Of California-Irvine	2/28/25
K01AG056669	The Epidemiology of Alzheimer's Disease and Related Dementias in Sexual and Gender Minority Older Adults: Identifying Risk and Protective Factors	University Of Nevada Las Vegas	2/28/25
OT2OD035935	Leveraging a community-driven approach to address the impact of social determinants of health on structural inequities among Miami-Dade County's intergenerational LGBTQ+ Community	Urban Health Partnerships	2/28/25
OT2OD035935-01S1	Leveraging a community-driven approach to address the impact of social determinants of health on structural inequities among Miami-Dade County's intergenerational LGBTQ+ Community	Urban Health Partnerships	2/28/25
R01AG063771	Effects of Social Networks and Policy Context on Health among Older Sexual and Gender Minorities in the US South	Vanderbilt University	2/28/25
R01MD012793	Advancing novel methods to measure and analyze multiple types of discrimination for population health research	Harvard School Of Public Health	2/28/25
R21AA029513	Health Effects of Intersectional Stigma among Sexual Minority Women	University Of California Santa Barbara	2/28/25
R21AA030373	Internal Sources of Minority Stress and Alcohol Consumption	Texas Tech University	2/28/25
R21CA284313	TRANSforma Tu Salud Dejando de Fumar: Advancing smoking cessation among transgender individuals	University Of Rochester	2/28/25
R21MD016457	Facilitators of and barriers to healthcare utilization among racially and ethnically diverse transgender and gender nonbinary young adults	University Of Central Florida	2/28/25
R21MD016962	Racialized Sexual Discrimination (RSD) and Psychological Well-being among Young Sexual Minority Men of Color (YSMMoC)	University Of Illinois At Urbana-Champaign	2/28/25
R44AG080843	SilverBills: A Legal, Technical and Financial Tool for Aging LGBTQ+ Individuals with Impaired Cognition.	Silverbills Inc.	2/28/25
R44AG080843-02S1	SilverBills: A Legal, Technical and Financial Tool for Aging LGBTQ+ Individuals with Impaired Cognition.	Silverbills Inc.	2/28/25
RF1MH132348	Improving mental health among the LGBTQ+ community impacted by the COVID-19 pandemic	Brown University	2/28/25
SC3GM136580	Trajectories of Adaptation to Traumatic Stress in a Vulnerable Population	Hunter College	2/28/25
U01MH136558	TransHealthGUIDE: Transforming Health for Gender-Diverse Young Adults Using Interventions to Drive Equity	Boston Children's Hospital	2/28/25
U24MD017138	FIRST Coordination and Evaluation Center to promote inclusive excellence	Morehouse School Of Medicine	3/1/25
F31GM153136	Understanding how chromosomal makeup and cross-sex hormone administration affect wound healing in mice	Johns Hopkins University	3/3/25
F31HL172648	Cross Sex Steroid Therapy and Cardiovascular Risk in the Transgender Female	University Of Mississippi Med Ctr	3/3/25
R01AI171984	The roles of genetics, hormones, and gender in sexually dimorphic immune response	Van Andel Research Institute	3/3/25
R01DK129239	Mitochondrial-based Determinants of Sex Differences in Acute Kidney Injury	University Of Alabama At Birmingham	3/3/25
R01HD098233	Reproductive Consequences of Steroid Hormone Administration	University Of Michigan At Ann Arbor	3/3/25
R01HD111650	Androgen effects on the reproductive neuroendocrine axis	University Of California, San Diego	3/3/25
R01HD115881	Microbiome mediated effects of gender affirming hormone therapy in mice	Emory University	3/3/25
R01MD019678	Mental Health Risk and Resilience among Latinx SGM Adolescents and their Parents	University Of Arizona	3/3/25
R21EB030851	Personalized 3D avatar tool development for measurement of body perception across gender identities	Centre For Addiction And Mental Health	3/3/25
F30HD107932	Enhancing K-12 School Safety During a Respiratory Viral Pandemic	Yale University	3/10/25
F31AI178878	Epidemiological factors related to human monkeypox virus (MPOX) in men who have sex with men (MSM) in the United States	Johns Hopkins University	3/10/25
K01DK125616	Implementation research to improve the uptake of influenza vaccination in CKD	Johns Hopkins University	3/10/25
K01MH132899	Using Data Science to Quantify the Impact of Misinformation, Mistrust, and Other Key Psychosocial Factors on Vaccine Hesitancy Among Vulnerable People Experiencing Psychopathology	University Of Minnesota	3/10/25
K23HD107184	Digital Storytelling to Reduce Pediatric Influenza Vaccination Disparities: A Pilot Pragmatic Trial	Denver Health And Hospital Authority	3/10/25
K23HD111624	Improving Vaccine Delivery in Hospitalized Children	Seattle Children's Hospital	3/10/25
K23HD112599	Caregiver decision making for seasonal respiratory vaccines for children	Children's Research Institute	3/10/25
R01AI165768	Population-level assessment of early childhood vaccination timeliness, parental vaccine hesitancy, and immunization schedule adherence in the United States, including rural-urban disparities	University Of Montana	3/10/25
R01AI166967	PROmotion of COVid-19 VA(X)ccination in the Emergency Department - PROCOVAXED	University Of California, San Francisco	3/10/25
R01AI169239	Uptake, Safety and Effectiveness of COVID,Âê19 Vaccines during Pregnancy	University Of San Francisco	3/10/25
R01AI170946	Alaska Native Communities Advancing Vaccine Uptake	Southcentral Foundation	3/10/25

R01AI182165	Text4Vax: Understanding the Effectiveness and Implementation of Text Message Reminders for Pediatric COVID-19 and Influenza Vaccines	Columbia University Health Sciences	3/10/25
R01EY028739	The Impact of the Herpes Zoster Vaccine on Herpes Zoster Ophthalmicus	University Of California, San Francisco	3/10/25
R01HD107753	Maternal COVID-19 Vaccination and Lactation Outcomes	Healthpartners Institute	3/10/25
R01HD110428	Modeling Adolescent Health Care Decision-Making for Vaccines: A Community- Based Participatory Approach	University Of Pittsburgh At Pittsburgh	3/10/25
R01HG012830	Religion and support for genomic healthcare: An exploratory study of the US public and faith leaders.	Washington University	3/10/25
R01MH132415	Understanding the Regional Ecology of a Future HIV Vaccine	University Of Pennsylvania	3/10/25
R01NR020482	Leveraging community-based behavioral health to increase vaccine uptake in Latinx adults with mental illness	Boston College	3/10/25
R15AI176375	COVID-19 Vaccine Uptake and Risk Mitigation Behaviors: Understanding the Role of Institutional Trust	Bentley University	3/10/25
R15GM152943	Mathematical Modeling and Scientific Computing for Infectious Disease Research	University Of Tennessee Chattanooga	3/10/25
R21AI182822	Covid-19 transmission, testing, and vaccination dynamics within migrant worker social networks	University Of Chicago	3/10/25
R21AI183544	Understanding transgender women's immune and behavioral responses to seasonal COVID-19 vaccines to improve their uptake	New York Blood Center	3/10/25
R21HD109536	Evaluating Teen-Parent Dynamics in Adolescent COVID-19 Vaccine Acceptance and Uptake	University Of San Francisco	3/10/25
R21HD110837	Reducing Vaccine Hesitancy among Hispanic Parents of COVID-19 Vaccine-Eligible Children	Arizona State University-Tempe Campus	3/10/25
R21HD110912	COVID19 vaccine hesitancy among perinatal women at risk for health disparities	Butler Hospital (Providence, Ri)	3/10/25
R25GM132758-03S1	One Health Education: Connecting Humans, Animals, and the Environment	University Of Rochester	3/10/25
R25GM132910-05S1	Partnerships for Prevention: A plan for managing student stress, anxiety, and pain through interactive¬†media.	Duquesne University	3/10/25
R35GM146974	Digital data streams and machine learning for real-time modeling of vaccine-preventable infectious diseases	Boston Children's Hospital	3/10/25
RF1MH132360	Brief digital intervention to increase COVID-19 vaccination among individuals with anxiety or depression	Graduate School Of Public Health And Health Policy	3/10/25
U54CA284030	The Empilisweni Center for Women's Health - Advancing Implementation of Equitable Cervical Cancer Control	Columbia University Health Sciences	3/10/25
U54GM115516	Northern New England Clinical and Translational Research Network	Mainehealth	3/10/25
U54GM115516-08S1	Northern New England Clinical and Translational Research Network - Equipment	Mainehealth	3/10/25
UH3DE030063	Investigating Behavioral Mechanisms and Efficacy of a Provider-Directed Intervention for HPV Vaccine Promotion in Real-World Dental Settings	Healthpartners Institute	3/10/25
R01AG089099	Social Networks and Cognitive Health among Black and Latino sexual minority men in NJ	Rutgers Biomedical And Health Sciences	3/11/25
R01DA058642	Testing a multistage model of risk factors for cannabis use utilizing a measurement burst design among sexual minority women, sexual minority gender diverse individuals, and heterosexual women	Ohio State University	3/11/25
R01HD075787-08S1	Social influences on sexual health among Latinx adolescents and emerging adults who identify as LGBTQ+ in an agricultural community	Research Triangle Institute	3/11/25
R01NR020846	#TranscendentHealth - Adapting an LGB+ inclusive teen pregnancy prevention program for transgender boys	Center For Innovative Public Health Research	3/11/25
F31ES034972	Prenatal exposure to phthalates and associations with gestational weight gain and fetal growth trajectories.	Columbia University Health Sciences	3/12/25
F31ES035280	An equity-focused evaluation of a system-wide intervention to reduce mold in NYC public housing and its impact on asthma burden	Columbia University Health Sciences	3/12/25
F31HD110257	Does self-reported psychosocial stress in pregnancy mediate the association between maternal race/ethnicity and hypertensive disorders of pregnancy?	Columbia University Health Sciences	3/12/25
F31MD019521	A multi-level study of the link between fear of deportation and mental health in Latinx young adults: The role of systemic inflammation and related risk and protective factors	University Of Houston	3/12/25
F31MH132290	Neighborhood Social Environment, Composition and Depression in Latinx	Columbia Univ New York Morningside	3/12/25
F31MH134699	Applying a multidimensional measure of human mobility to understand drivers of HIV incidence in Rakai, Uganda	Columbia University Health Sciences	3/12/25
F31MH138075	Intersectional Discrimination and Sexual Health Among Young Black Men who Have Sex with Men: A Mixed Methods Study	Duke University	3/12/25
F32AA029957	Understanding the individual and combined impact of childhood sexual abuse and minority stress on hazardous drinking among sexual minority women: Is emotion dysregulation a key factor?	Columbia University Health Sciences	3/12/25
F32MH135634	The psychological underpinnings of gender disparities in adolescent mental health	Princeton University	3/12/25
G13LM014176	Diversity in Practice: the Quest for Inclusion in Precision Medicine	Columbia University Health Sciences	3/12/25

G13LM014426	Securing Health Equity: Philosophical Foundations for Equality and Social Justice in Public Health and Health Care	University Of Washington	3/12/25
K01MH120258	Youth-PRIDES: Implementing integrated, mHealth care for adolescent depressionwithin primary care clinics of Mozambique	Columbia University Health Sciences	3/12/25
K23AI150378	Harnessing Bioinformatics for HIV Prevention: Understanding Persistence in Comprehensive HIV Prevention Services	Columbia University Health Sciences	3/12/25
K23NS130143	Effect of pubertal hormones on Headache in Transmasculine Adolescents	University Of Colorado Denver	3/12/25
K24DA051328	Mentoring clinical investigators in patient-oriented research on substance use and HIV	Columbia University Health Sciences	3/12/25
P50MD019473	Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers	State University Of New York At Buffalo	3/12/25
R01AA030275	An intersectional approach linking Minority Stressors Experienced by Transgender and Gender Diverse Adults to Alcohol and Drug Use and comorbid Mental and Physical Health Outcomes	Georgia State University	3/12/25
R01CA253368	The linkage between Race, Kaiso and the tumor microenvironment in breast cancer health disparities	Columbia University Health Sciences	3/12/25
R01CA254576	Automated Digital Imaging for Cervical Cancer Screening	Columbia University Health Sciences	3/12/25
R01DA043512	Preventing Drug Abuse among Sexual-Minority Youth	Columbia Univ New York Morningside	3/12/25
R01DA045713	A Multi-site Multi-Setting RCT of Integrated HIV Prevention and HCV Care for PWID	Columbia University Health Sciences	3/12/25
R01DA054236	Project SMART: Social Media Anti-vaping Messages to Reduce ENDS Use Among Sexual and Gender Minority Teens	University Of Pennsylvania	3/12/25
R01DA054236-04S1	Project SMART: Social Media Anti-vaping Messages to Reduce ENDS Use Among Sexual and Gender Minority Teens	University Of Pennsylvania	3/12/25
R01DA061247	SILOS: Structural Inequities across Layers Of Social-Context as Drivers of HIV and Substance Use	Northwestern University At Chicago	3/12/25
R01DK122564-05S1	Skeletal Health in Youth with Type 1 Diabetes and Gender Diversity	Columbia University Health Sciences	3/12/25
R01HD092347-08S1	Views of Gender in Adolescence	Princeton University	3/12/25
R01HD094081	A Longitudinal Examination of Mechanisms Underlying Intersectional Health Disparities in the United States	University Of Minnesota	3/12/25
R01HD104599	Obesogenic origins of maternal and child metabolic health involving dolutegravir (ORCHID)	Columbia University Health Sciences	3/12/25
R01HG010868	Disability, diversity and trust in precision medicine research: stakeholdersengagement	Columbia University Health Sciences	3/12/25
R01MD013495	Health disparities, stress pathways, and stress-related comorbidities among MSM living with HIV	Johns Hopkins University	3/12/25
R01MD013554	Impact of Social Cohesion and Social Capital in PrEP Uptake and Adherence Among Transwomen of Color	Columbia University Health Sciences	3/12/25
R01MD016082	Efficacy of a Multi-level School Intervention for LGBTQ Youth	Washington University	3/12/25
R01MD016384	An Innovative, Prospective Model to Understand Risk and Protective Factors for Sexual Assault Experiences and Outcomes Among Sexual Minority Men	University Of Nebraska Lincoln	3/12/25
R01MD019178	A Multi-Level Trauma-Informed Approach to Increase HIV Pre-exposure Prophylaxis Initiation among Black Women	Johns Hopkins University	3/12/25
R01MD019956	Theoretically Informed Behavioral Intervention to Enhance QOL and Prevent HIV-related Comorbidities in Ethnic and Racial Sexual Minority Men	Yale University	3/12/25
R01MD020284	Measures of structural stigmatization and discrimination for HIV research with Latine sexual and gender minorities	Drexel University	3/12/25
R01MH116829	Building mobile HIV prevention and mental health support in low-resource settings	Columbia University Health Sciences	3/12/25
R01MH118004	A randomized trial of ImpACT+, a coping intervention to improve clinical and mental health outcomes among HIV-infected women with sexual trauma in South Africa	Columbia University Health Sciences	3/12/25
R01MH121194	Monitoring Microaggressions and Adversities to Generate Interventions for Change (MMAGIC) for Black Women Living with HIV	University Of Miami Coral Gables	3/12/25
R01MH121194-04S1	Monitoring Microaggressions and Adversities to Generate Interventions for Change (MMAGIC) for Black Women Living with HIV	University Of Miami Coral Gables	3/12/25
R01MH130166	Multilevel Racism & Discrimination and PrEP Outcomes Among Black SMM in the Southeastern U.S.	Us Helping Us, People Into Living, Inc.	3/12/25
R01MH133821	The Socioecology of Sexual Minority Stigma: Data Harmonization to Address Confounding Bias and Investigate Cross-Level MentalHealth Effects	San Diego State University	3/12/25
R01NR019417	Sex, Hormones and Identity affect Nociceptive Expression (SHINE)	University Of Alabama At Birmingham	3/12/25
R01NR020154-04S1	Exploring Stigma, Social Support, and Cancer Screenings among Sexual and Gender Diverse People Living with HIV in Georgia	Emory University	3/12/25
R01NR021691	Identifying multilevel facilitators of care outcomes among Positive Deviants to design an intervention for Black sexual minority men living with HIV	George Washington University	3/12/25
R03ES035509	Drinking water contaminants and fetal loss in Northern California	Columbia University Health Sciences	3/12/25

R13HD110322	International Workshops on HIV Pediatrics	Columbia University Health Sciences	3/12/25
R13MH138043	National LGBT Health Conference 2024	Emory University	3/12/25
R21AI171249	Multimodal immune profiling to determine mechanisms of COVID-19 clinical trajectory in Uganda	Columbia University Health Sciences	3/12/25
R21AI175747	Using wastewater surveillance data to study SARS-CoV-2 dynamics and predict COVID-19 outcomes	Columbia University Health Sciences	3/12/25
R21AI178913	Understanding the effects of cross-sex hormone therapy on vaginal mucosal immunity	Boston Medical Center	3/12/25
R21HD103053	mHealth and Mobile Ultrasound for Mothers	Columbia University Health Sciences	3/12/25
R21MD018509	Development and Pilot Evaluation of an Online Mentoring Program to Prevent Adversities Among Trans and Other Gender Minority Youth	University Of Nebraska Lincoln	3/12/25
R21MH127356	Investigating associations and mediating effects between climate and mental health and violence in informal settlements in Kenya	Columbia Univ New York Morningside	3/12/25
R21MH133755	The TAIL-PrEP Study: Acceptability and Feasibility of a Tailored Adherence Intervention for safe discontinuation of Long-acting PrEP	Columbia University Health Sciences	3/12/25
R21MH135489	Leveraging Latinx Adolescents, Photovoice, and Longitudinal Data to Disentangle the Bidirectional Effects of Social Media and Mental Health	Columbia University Health Sciences	3/12/25
R24DA061190	PRIDE-CARES Center: Patient-Responsive Initiatives for Diverse Engagement - LGBTQ+ Community Action in Research to Eliminate Substance Use Disorder	University Of South Carolina At Columbia	3/12/25
R25GM109435	PREP at University of Georgia	University Of Georgia	3/12/25
R25GM149980	Developing Modules to Address Microaggressions and Discriminatory Behaviors	Children's Hosp Of Philadelphia	3/12/25
R25HD074544	Fragile Families Summer Data Training Workshop Series 2021-2025	Columbia Univ New York Morningside	3/12/25
R25HG010857	Genomics Diversity Summer Program (GDSP) at Stanford	Stanford University	3/12/25
R25HL096260	BEST-DP: Biostatistics & Epidemiology Summer Training Diversity Program	Columbia University Health Sciences	3/12/25
R25MH080665	HIV Intervention Science Training Program for Underrepresented Investigators	Columbia Univ New York Morningside	3/12/25
R33TW011752	Preparing for pre-exposure prophylaxis implementation in Central-Eastern European Countries with low access to biomedical prevention	Columbia University Health Sciences	3/12/25
R34MH128163	Development and Testing of MyPEEPS Mobile for Young Transgender Men	Columbia University Health Sciences	3/12/25
R34MH136018	Development of a School-Based Prevention Intervention to Promote Adolescent Mental Health Equity	Boston College	3/12/25
R35GM157032	Molecular Mechanisms of Hormone-Mediated Sex Differences in Wound Healing	Brigham And Women's Hospital	3/12/25
R36DA058830	Exploring Historical Trauma, Racial Discrimination, PTSD, and Substance Use Among Black Young Adults	New School University	3/12/25
R56CA284564	Gender-Affirming Testosterone Therapy on Breast Cancer Risk and Treatment Outcomes	Beth Israel Deaconess Medical Center	3/12/25
R61HD117134	Supportive and restrictive factors and mental health in LGBT adolescent and young adult populations	Harvard Pilgrim Health Care, Inc.	3/12/25
T32AI106711	Columbia University Graduate Training Program in Microbiology and Immunology	Columbia University Health Sciences	3/12/25
T32MH016434	Translational Research Training in Child Psychiatry	Columbia University Health Sciences	3/12/25
T32MH018870	Training in Schizophrenia and Psychotic Disorders: From Animal Models to Patients	Columbia University Health Sciences	3/12/25
T32MH019139	Behavioral Sciences Research in HIV Infection	Columbia University Health Sciences	3/12/25
T32MH020004	Research Training in Late-Life NeuroPsychiatric Disorders	Columbia University Health Sciences	3/12/25
T32MH126772	Culturally-focused HIV Advancements through the Next Generation for Equity (CHANGE) Training Program	University Of Miami School Of Medicine	3/12/25
U01HD108779	Unequal Parenthoods: Population Perspectives on Gender, Race, and Sexual Minority Disparities in Family Stress and Health During Crises	University Of Minnesota	3/12/25
U01MH125058	2/3 Genomics of Schizophrenia in the South African Xhosa	Columbia University Health Sciences	3/12/25
U54CA272171	Faculty Initiative for Improved Recruitment, Retention, and Experience (FIIRRE)	University Of South Carolina At Columbia	3/12/25
UM1TR004409	CTSA UM1 Program at University of Utah	University Of Utah	3/12/25
D43TW012189	Guyana Research in Injury and Trauma Training (GRITT) Program	Columbia University Health Sciences	3/14/25
DP2DA058436	ENTRUST - economic navigation and strengthening to realize unrestricted services for transgender women	University Of Central Florida	3/14/25
DP2MH132941	The Optics of Health: Race Skin Tone Minority Health and Health Disparities in the U.S.	Harvard University	3/14/25
DP5OD031849	Public Drinking Water Contaminants and Infant Health: Advancing Environmental Justice	Columbia University Health Sciences	3/14/25
DP5OD037400	The Behavioral Cost of Carbon	Columbia University Health Sciences	3/14/25
F30HD108886	Quantifying the interactions among maternal race, vaginal metabolites, and microbes in preterm birth	Columbia University Health Sciences	3/14/25
F31AI176760	Host Factors Required by Human Parainfluenza Virus 3: Determinants of entry and viral spread	Columbia University Health Sciences	3/14/25

F31AI176851	Investigating the potential of wastewater surveillance data to improve SARS-CoV-2 dynamical modeling and forecasting	Columbia University Health Sciences	3/14/25
F31HD115324	Associations among maternal stress, infant epigenetics, and behavioral and cognitive development across the first few years of life	Columbia University Teachers College	3/14/25
F31NR021239	Personal Healthcare Networks of Transgender and Gender-Diverse Adults After Gender-Affirming Surgery	Columbia University Health Sciences	3/14/25
F31NR021330	The Role of Social Determinants in Reproductive Coercion: Understanding Health Information and Support Needs	Columbia University Health Sciences	3/14/25
F31NS130983	Type I Interferon Mediated Restoration of Brain Endothelial Cell Function after Cerebral Infarction	Columbia University Health Sciences	3/14/25
K01AA028532	Alcohol-Involved Sexual Assault among Bisexual Women: Disentangling Mechanisms of Risk at Individual, Interpersonal, and Structural Levels Across the Lifespan	Columbia University Health Sciences	3/14/25
K23AI163364	Subtyping sepsis in Uganda using clinical, pathogen, and host response profiling	Columbia University Health Sciences	3/14/25
K23AI171263	Evaluating the Epidemiology and Determinants of Neurologic Post-acute Sequelae of SARS-CoV-2	Columbia University Health Sciences	3/14/25
K23DC019678	Neurocognitive & neuropsychiatric impact of chemosensory alterations: Implications of olfactory dysfunction in COVID-19	Columbia University Health Sciences	3/14/25
K99ES035895	Spatiotemporal effects and associations between deforestation and alcohol and tobacco use in Indonesia	Columbia University Health Sciences	3/14/25
OT2OD025276	PRIDEnet for the All of Us Research Program	Stanford University	3/14/25
P20AG093975	Climate and Health: Action and Research for Transformational Change (CHART)	Columbia University Health Sciences	3/14/25
P20TW012808	Anga Center for Climate Justice, Health Equity, and Community Wellbeing	Columbia Univ New York Morningside	3/14/25
P30ES009089	Center for Environmental Health and Justice in Northern Manhattan	Columbia University Health Sciences	3/14/25
P50MD017341	Center to Improve Chronic disease Outcomes through Multi-level and Multi-generational approaches Unifying Novel Interventions and Training for health EquitY (The COMMUNITY Center)	Columbia University Health Sciences	3/14/25
P50MD017341-04S2	Center to Improve Chronic disease Outcomes through Multi-level and Multi-generational approaches Unifying Novel Interventions and Training for health EquitY (The COMMUNITY Center)	Columbia University Health Sciences	3/14/25
R00ES033742	Novel Assessments of the Health Impacts of Tropical Cyclones	Columbia University Health Sciences	3/14/25
R01AI151173	Targeting TB transmission hotspots to find undiagnosed TB in South Africa: a genomic, geospatial and modeling study (TARGET- TB)	Columbia University Health Sciences	3/14/25
R01AI160953	Fusion inhibitors that block host-to-host transmission of SARS-CoV-2	Columbia University Health Sciences	3/14/25
R01AI160961	Engineering protease-resistant antiviral peptide inhibitors for SARS-CoV-2	Columbia University Health Sciences	3/14/25
R01CA274564	Impact of Allostatic Load and Neighborhood Contextual Factors on Breast Cancer in the Women's Health Initiative	Columbia University Health Sciences	3/14/25
R01CA279145	SPECTRUM (Studying PRIDE to Enhance Cancer screening guidelines for TRansgender Users of gender-affirMing hormones)	Columbia University Health Sciences	3/14/25
R01DA054553	Cannabis use, PrEP and HIV transmission risk Among Black MSM in Chicago	Columbia University Health Sciences	3/14/25
R01HD105492	Trial of Human Milk Oligosaccharide-based synbiotics for HIV-exposed uninfected children	Columbia University Health Sciences	3/14/25
R01HG012841	Just Inclusion and Equity: Negotiating Community-Research Partnerships in Genomics Research (JUSTICE)	Columbia University Health Sciences	3/14/25
R01HG012841-02S1	Just Inclusion and Equity: Negotiating Community-Research Partnerships in Genomics Research (JUSTICE)	Columbia University Health Sciences	3/14/25
R01HL160325	Characterizing Sleep, ART Adherence and Viral Suppression Among Black Sexual Minority Men	Columbia University Health Sciences	3/14/25
R01MD016386	Racial Disparity in Diagnostic Evaluation of Uterine Cancer	Columbia University Health Sciences	3/14/25
R01MD017509	Universal basic income and structural racism in the US South: Differences in health service utilization between older African American men with and without experiences of recent incarceration	Univ Of Arkansas For Med Scis	3/14/25
R01MD018250	Assessing Cervical Cancer Healthcare Inequities in Diverse Populations: The ACHIEVE Study	Columbia University Health Sciences	3/14/25
R01MH126531	COVID-19 Mother Baby Outcomes (COMBO): brain-behavior functioning	Columbia University Health Sciences	3/14/25
R01MH128734	Temperature, shade, and adolescent psychopathology: understanding how place shapes health	Columbia University Health Sciences	3/14/25
R01NR020583	Ending the HIV Epidemic with Equity: An All-facility Intervention to Reduce Structural Racism and Discrimination and Its Impact on Patient and Healthcare Staff Wellbeing	Columbia University Health Sciences	3/14/25
R13EB035037	Summer Biomechanics, Bioengineering, and Biotransport Conference	Columbia University Health Sciences	3/14/25
R21HD115480	Strengthening informed consent for authentic participation in perinatal HIV research	Columbia University Health Sciences	3/14/25
R25ES036012	Bronx Environmental Health Summer Training for Justice	Columbia University Health Sciences	3/14/25
R25HL156002	Training in Cardiovascular Sciences for Under Represented Students	Columbia University Health Sciences	3/14/25
R25HL161786	Summer Institute for Training in Biostatistics and Data Science at Columbia (SIBDS@Columbia)	Columbia University Health Sciences	3/14/25

R25NS130961	CADRE Program for Postbaccalaureate Training in the Neurosciences	Columbia University Health Sciences	3/14/25
R33CA253604	SEARCH: SMS Electronic Adolescent Reminders for Completion of HPV vaccination- Uganda	Columbia University Health Sciences	3/14/25
R36DA061635	Dissecting the role of loneliness on substance use- and HIV-related outcomes among sexual minority men in the United States and Canada	Columbia University Health Sciences	3/14/25
R56AI182347	Doxy4STICare - Doxycycline for Sexually Transmitted Infections; A Comprehensive Assessment of Antimicrobial Resistance and Engagement	Columbia University Health Sciences	3/14/25
R61DA058985	Structural Racism, Neurocognition in Reward Related Decision Making and Substance Use Risk	Columbia University Health Sciences	3/14/25
T32DK007328	Hormones: Molecular Mechanism of Action and Functions	Columbia University Health Sciences	3/14/25
T32GM141882	Genetic Approaches to Development and Disease	Columbia University Health Sciences	3/14/25
T32MH128395	Social Determinants of HIV	Columbia University Health Sciences	3/14/25
T32NR007969	Reducing Health Disparities Through Informatics	Columbia University Health Sciences	3/14/25
T35HL007616	Short Term Training Grant	Columbia University Health Sciences	3/14/25
U01DK130058	India - Factors of CKDu in Uddanam Study (India-FOCUS)	Columbia University Health Sciences	3/14/25
U01NS135533	The SDOH-Homecare Intervention Focus Team (SHIFT) Trial to Mitigate SDOH in Stroke Outcomes and Build Community Capacity	Columbia University Health Sciences	3/14/25
U2RTW012123	Advancing Public Health Research in Eastern Africa through Data Science Training (APHREA-DST)	Columbia University Health Sciences	3/14/25
U54HD113172	NY Community-Hospital-Academic Maternal Health Equity Partnerships (NY-CHAMP)	Columbia University Health Sciences	3/14/25
F31AA031605	A Mixed Methods Study to Enhance Alcohol Treatment Help-seeking and Engagement Among Gender Diverse Adults	University Of Memphis	3/18/25
F31AA031618	Post-Traumatic Stress and Alcohol Use as Mechanisms Explaining IPV Among Bisexual Women Who Disclose Sexual Violence to Partners: Examining Minority Stress as a Moderator	University Of Nebraska Lincoln	3/18/25
F31AI181431	Prevention of Chlamydia trachomatis infections: Evaluation of vaccination and post-exposure prophylactic antibiotic use as population-level strategies	University Of Washington	3/18/25
F31DA062473	Social safety as a novel mechanism of risk for problematic substance use among sexual and gender minority youth	Univ Of North Carolina Chapel Hill	3/18/25
F31MD019985	Characterizing Economic Determinants of Violence and Safety Disparities Among Sexual and Gender Diverse Populations	Johns Hopkins University	3/18/25
F31MH134720	Understanding Patient Level Implementation Determinants Related to Long-acting Injectable HIV Pre-Exposure Prophylaxis among Young Men Who Have Sex with Men Living in Rural Areas	Medical College Of Wisconsin	3/18/25
F31MH136729	Determining the role of discrimination in clinical presentation and treatment response among sexual minority people with OCD: A machine learning approach	Fordham University	3/18/25
F31MH136856	Aligning HIV services with gender diverse community priorities through person-centered care: a mixed methods study in India	Johns Hopkins University	3/18/25
F31MH138212	Exploring Acceptability & Potential Reach of Game-Based & Social Network Strategies for Improving PrEP & HIV Self-Testing Uptake among Latinx Sexual Minority Men Living in an EHE Priority Jurisdiction	University Of Miami School Of Medicine	3/18/25
F31MH139225	Structural Stigma and Mental Health Among Transgender and Gender Diverse Adults Living in the Rural United States	Johns Hopkins University	3/18/25
F31MH139392	HIV risk messaging and medical mistrust in the era of Undetectable=Untransmittable: Psychosocial and Behavioral Implications among Black, Latino/a/e/x, and Multiracial Sexual and Gender Minorities	George Washington University	3/18/25
F31NR021243	Intergenerational and Cultural Drivers of Depressive Symptoms in Hispanic Sexual Minority Youth	University Of Miami Coral Gables	3/18/25
F31NR021247	Client and clinician priorities for same-day PrEP and DoxyPEP awareness, uptake, and persistence in primary care.	Ohio State University	3/18/25
F32MH138253	Training in Behavioral Design Interventions to Address Stigma among Men Who have Sex with Men	Yale University	3/18/25
K23MH134111	Using youth-engaged methods to develop and evaluate a measure for disordered eating behaviors in transgender and gender-diverse youth	Virginia Commonwealth University	3/18/25
K23MH137389	ALIVE: Development and feasibility of a psychosocial intervention for sexual and gender minority autistic adults	Hunter College	3/18/25
K43TW012850	Adapting an evidence-based intervention to improve HIV testing and PrEP uptake among young men who have sex with men in Vietnam	Hanoi Medical University	3/18/25
T32MH130325	Training Program in Translational Science, HIV, and Sexual and Gender Minority Health	Northwestern University At Chicago	3/18/25
F31AA031420	Examining Proximal Associations between Minority Stress, PTSD Symptoms, and Alcohol Use among Bi+ College Students with Trauma Histories	University Of Tennessee Knoxville	3/19/25
K23DK139454	Structural Racism as a "Third hit" on kidney outcomes of Black individuals with APOL1 risk alleles	Icahn School Of Medicine At Mount Sinai	3/20/25
P2CHD058486	Columbia Population Research Center	Columbia Univ New York Morningside	3/20/25
P50MD019475	The Institute for Health Equity Research Catalyst Center	Icahn School Of Medicine At Mount Sinai	3/20/25

R01AA031637	The Role of Local Structural Stigma in Alcohol Related Inequities among SGM Young Adults	Pacific Institute For Res And Evaluation	3/20/25
R01AI145675	Improving PrEP protection of transgender women through mechanistic pharmacokinetic understanding	Johns Hopkins University	3/20/25
R01AI154541	Sex, Gender and the Immunopathogenesis of HIV	Johns Hopkins University	3/20/25
R01AI169643	FINISHING HIV: An EHE model for Latinos Integrating One-Stop-Shop PrEP Services, a Social Network Support Program and a National Pharmacy Chain	University Of Miami School Of Medicine	3/20/25
R01AI172092	Enhanced COhort methods for HIV Research and Epidemiology (ENCORE) among transgender women in the United States	Johns Hopkins University	3/20/25
R01AI172469	Examining Social Ecological and Network Factors to Assess Epidemiological Risk in a Large National Cohort of Cisgender Women	Columbia University Health Sciences	3/20/25
R01AI174862	Cabotegravir PrEP: Actionable Robust Evidence for Translation into Practice (CABARET)	Harvard Pilgrim Health Care, Inc.	3/20/25
R01AI181732	The Doxy-PEP Impact Study: a multi-city US longitudinal cohort to evaluate doxy-PEP field effectiveness, investigate associated antimicrobial resistance, and establish doxy-PEP to need ratios	University Of California, San Francisco	3/20/25
R01AI186641	Randomized Directly Observed Therapy Study to Interpret Clinical Trials of Doxy-PEP	University Of California, San Francisco	3/20/25
R01AI189309	Impact of Gender Affirming Hormone Therapy on HIV Viral Dynamics and Immune Responses in Transgender Women	Johns Hopkins University	3/20/25
R01CA237670	Project RESIST: Increasing Resistance to Tobacco Marketing Among Young Adult Sexual Minority Women Using Inoculation Message Approaches	University Of Pennsylvania	3/20/25
R01CA253244	HPV Oropharyngeal cancer and screening in Gay and Bisexual Men	University Of Minnesota	3/20/25
R01CA265945	Testing Effective Methods to Recruit Sexual and Gender Minority Cancer Patients for Cancer Studies	University Of Minnesota	3/20/25
R01CA276500	Smoking and Cancer-Related Health Disparities among Sexual and Gender Minority Adults	University Of Michigan At Ann Arbor	3/20/25
R01CA285198	Screening strategies and social determinants of health among people with high risk of anal cancer	Emory University	3/20/25
R01DA045773	Reducing Black Men's Drug Use and Co-Occurring Negative Mental and Physical Health Outcomes: Intersectionality, Social-Structural Stressors, and Protective Factors	George Washington University	3/20/25
R01DA052016	Substance use and DNA methylation at the intersection of sex and gender	University Of California, San Francisco	3/20/25
R01DA056888	Optimizing PrEP Implementation and Cost-effectiveness among Sexual and Gender Minority Individuals with a Substance Use Disorder	Friends Research Institute, Inc.	3/20/25
R01DA057351	Heavy cannabis use, neurocognition and PrEP care engagement among young Black sexual minority men	University Of Chicago	3/20/25
R01DA057351-03S1	Heavy cannabis use, neurocognition and PrEP care engagement among young Black sexual minority men	University Of Chicago	3/20/25
R01DA058965	Achieving Equity in Patient Outcome Reporting for Timely Assessments of Life with HIV and Substance Use (ePORTAL HIV-S)	University Of Chicago	3/20/25
R01DA058994	Network-based study design, statistical, and modeling solutions for HIV among populations that use illicit substances: Informing interventions and policy in real-world settings using existing data	University Of Rhode Island	3/20/25
R01DA059240	Characterizing Intersectional Geospatial Stigma and Affirmation Landscapes and Their Influence on Black and Latino Bisexual Men At Risk for Substance Abuse and HIV	Florida State University	3/20/25
R01DA061345	Race & Place: The Impacts of Racial Inequality on Substance Use and HIV Outcomes in Los Angeles	University Of California Los Angeles	3/20/25
R01DA061661	Optimizing a Just-in-Time Adaptive Intervention to Increase Uptake of Chemsex Harm Reduction Services in MSM: A Micro-randomized Trial	University Of Connecticut Storrs	3/20/25
R01DC020061	Effects of exogenous testosterone therapy on communication in gender diverse speakers	Boston University (Charles River Campus)	3/20/25
R01DE032225	The Role of Testosterone on Mediating Sex and Gender Influences on Chronic Orofacial Pain Conditions	University Of Maryland Baltimore	3/20/25
R01ES036258	Reframing personal and community report back of consumer products by centering intersectionality	Columbia University Health Sciences	3/20/25
R01HD100180	Female Sexual Orientation GWAS	Endeavor Health Clinical Operations	3/20/25
R01HD101421	Skeletal Health and Bone Marrow Composition Among Youth	Boston Children's Hospital	3/20/25
R01HD112418	Long-term trajectories of psychosocial functioning among transgender youth and their parents.	Ut Southwestern Medical Center	3/20/25
R01HD114134	Equitable Measurement of Care Disparities and Needs in Intersex Youth/Youth with Variations in Sex Development	Children's Research Institute	3/20/25
R01HG012697	A novel approach for equitable characterization of gender and its use in exposing subgroup discrepancies in polygenic score associations	University Of Iowa	3/20/25
R01HG013145	Trans/Forming Genomics: Guidance for Research Involving Transgender and Gender Diverse People	Icahn School Of Medicine At Mount Sinai	3/20/25
R01HL149778	Cardiovascular Health of Sexual and Gender Minorities in the Hispanic Community Health Study/Study of Latinos (SGM HCHS/SOL)	Univ Of North Carolina Chapel Hill	3/20/25
R01HL160326	Stigma and the non-communicable disease syndemic in aging HIV positive and HIV negative MSM	Rutgers Biomedical And Health Sciences	3/20/25

R01HL165686	Synergistic epidemics of non-communicable diseases, stigma, depression, and material insecurities among sexual and gender minorities living with HIV in Nigeria	University Of Maryland Baltimore	3/20/25
R01LM013301	UnBIASED: Understanding Biased patient-provider Interaction And Supporting Enhanced Discourse	University Of Washington	3/20/25
R01MD014722	Still Climbin': A Randomized Controlled Trial of an Intervention to Improve Coping with Discrimination, Address Medical Mistrust, and Reduce Health Disparities among Black Sexual Minority Men	Rand Corporation	3/20/25
R01MD015109	Charting Trajectories of Sexual Identity Development and Mental Health Disparities Among Sexual Minority Youth	Univ Of North Carolina Chapel Hill	3/20/25
R01MD016417	Contextual Determinants of Sexual Minority Health in the United States	University Of Texas San Antonio	3/20/25
R01MD018051	Modeling Resilience as a Multidimensional Protective Factor for Transgender Health Disparities: Measure Development and Longitudinal Evaluation of Resilience	Michigan State University	3/20/25
R01MD018167	Sexual minority couples' health during the transition to marriage	University Of Denver (Colorado Seminary)	3/20/25
R01MD018340	Investigating and identifying the heterogeneity in COVID-19 misinformation exposure on social media among Black and Rural communities to inform precision public health messaging	University Of Pennsylvania	3/20/25
R01MD018523	A Multilevel, Multiphase Optimization Strategy for PrEP: Patients and Providers in Primary Care	Henry Ford Health + Michigan State University Health Sciences	3/20/25
R01MD018571	A multidimensional investigation of social support for transgender and nonbinary people and its impacts on health and well-being: Measurement development using community engagement	University Of Wisconsin-Madison	3/20/25
R01MD018679	Understanding the Role of Structural Oppression for Suicide Risk among Black Sexual and Gender Minority Adolescents and Young Adults	Rutgers Biomedical And Health Sciences	3/20/25
R01MD019181	MyPEEPS Mobile Plus: A Multi-Level HIV Prevention Intervention for Young MSM¬†	Columbia University Health Sciences	3/20/25
R01MD019278	Examining the Mechanisms and Consequences of Sleep Health Inequities Affecting Black Sexual Minority Men	Rand Corporation	3/20/25
R01MH100028	Autism Center of Excellence Network: Neurodevelopmental Biomarkers of Late Diagnosis in Female and Gender Diverse Autism	University Of Virginia	3/20/25
R01MH115349	Sex hormone effects on neurodevelopment: Controlled puberty in transgender adolescents	Stanford University	3/20/25
R01MH115765	A couples-based approach to HIV prevention for transgender women and their male partners	University Of Michigan At Ann Arbor	3/20/25
R01MH118245	Biopsychosocial mechanisms underlying internalizing psychopathology in a prospective, population-based cohort of sexual minority young adults	Yale University	3/20/25
R01MH119015	Addressing the continuum of care among high-risk Thai men	Mahidol University	3/20/25
R01MH119956	PrEP-3D: An Integrated Pharmacy Digital Diary and Delivery Strategy to Increase PrEP Use Among MSM	Public Health Foundation Enterprises	3/20/25
R01MH121256	Promoting Reductions in Intersectional Stigma to Improve HIV Testing and PrEP Use Among Latino Sexual Minority Men	Rand Corporation	3/20/25
R01MH123282	NEXUS: A novel social network approach to study the effects of intersectional stigma on HIV prevention among Latino MSM	University Of California, San Diego	3/20/25
R01MH123349	Social and structural violence and HIV care continuum outcomes: Developing a trauma-informed HIV care intervention among WLWH	University Of British Columbia	3/20/25
R01MH123388	Violence and viral suppression among men living with HIV	University Of Michigan At Ann Arbor	3/20/25
R01MH123746	THE IMPACT OF PUBERTAL SUPPRESSION ON ADOLESCENT NEURAL AND MENTAL HEALTH TRAJECTORIES - Resubmission - 1	Research Inst Nationwide Children's Hosp	3/20/25
R01MH124900	Social-Affective Vulnerability to Suicidality among LGBTQ Young Adults: Proximal and Distal Factors	University Of Pittsburgh At Pittsburgh	3/20/25
R01MH125727	PrEParados: A Multi-Level Social Network Model to Increase PrEP Enrollment by Latino MSM Self-Identified as Gay, Bisexual	University Of Miami School Of Medicine	3/20/25
R01MH128049	Tcher, Take Charge: Increasing PrEP Awareness, Uptake, and Adherence Through Health Care Empowerment and Addressing Social Determinants of Health Among Racially Diverse Trans Women in the Deep South	Public Health Foundation Enterprises	3/20/25
R01MH128130	STI Response and Recommendations Under PrEP (STIRRUP)	Emory University	3/20/25
R01MH131475	Intervention to Enhance PrepPersistence Among African American Men Who Have Sex With Men	Brown University	3/20/25
R01MH132147	Scaling Up Implementation Strategies to Improve the DIAGNOSE and PREVENT Pillars for Young MSM in Florida	Florida State University	3/20/25
R01MH132692	Young Sexual Minority Women's Mental Health: Developmental Trajectories, Mechanisms of Risk, and Protective Factors.	University Of Cincinnati	3/20/25
R01MH137695	Measuring and Mapping Trajectories of Risk and Resilience for Suicidal Thoughts and Behaviors in Sexual and Gender Minority Preteens	Vanderbilt University	3/20/25
R01MH138237	Leveraging a Strategic Alliance of Community-Based Implementers and Researchers to Characterize, Protocolize, and Scale Up Local Implementation Strategies for Ending the HIV Epidemic among Latino MSM	University Of Miami Coral Gables	3/20/25
R01MH138335	Bisexual adolescents' and young adults' risk for depression and suicidal ideation: Developmental trajectories, risk and protective factors, and underlying mechanisms	Ohio State University	3/20/25

R01MH140023	Mental Health Effects of Marriage Policy: Evidence from Linked Administrative Data in New Zealand	Vanderbilt University	3/20/25
R01NR021461	Examining Non-Congregate Shelter Effects on Mental Health Crises through Community Health Partnerships in Connecticut	Yale University	3/20/25
R03AA031740	Romantic Relationships, Discrimination Stressors, and Alcohol Use among Sexual and Gender Minority Adults	Montana State University - Bozeman	3/20/25
R03CA289560	Refinement of a Training Module to Improve Discussions of Sexual Orientation and Gender Identity in Cancer Clinics	Mayo Clinic Rochester	3/20/25
R13AI188929	2025 Sex Differences in Immunity Gordon Research Conference and Gordon Research Seminar	Gordon Research Conferences	3/20/25
R13HD117635	Be Curious, Not Judgmental: The 4th National Symposium on Sexual Behavior of Youth	University Of Oklahoma Hlth Sciences Ctr	3/20/25
R13HL177880	2025 Cardiac Arrhythmia Mechanisms Gordon Research Conference and Gordon Research Seminar	Gordon Research Conferences	3/20/25
R13MH136663	Enhancing Diversity, Equity, and Inclusion in Mental Health Research: American Psychopathological Association Annual Meetings	New York State Psychiatric Institute Dba Research Foundation For Mental Hygiene, Inc	3/20/25
R15AA030898	Reconstruction of an SGM-specific sexual violence peer support program (SSS+)	University Of North Carolina Charlotte	3/20/25
R21AA031548	Daily Impact of Sexual Minority Stress on Alcohol-Related Intimate Partner Violence among Bisexual+ Young Adults: A Couples' Daily Diary Study	Virginia Polytechnic Inst And St Univ	3/20/25
C06OD034040	Developing a Community-Based Facility to Support Next Generation Biomedical HIV Research	Whitman-Walker Institute, Inc.	3/21/25
C06OD034042	Meharry HIV/AIDS Research and Training Facility	Meharry Medical College	3/21/25
D43TW011324	Malaysian Implementation Science Training (MIST) Program in HIV	Yale University	3/21/25
D43TW012274	Integrated Networks of Scholars in Global Health Research Training (INSIGHT)	University Of Maryland Baltimore	3/21/25
DP2MH132938	Transdiagnostic Intervention to Reduce Internalized Health-Related Stigma	University Of Florida	3/21/25
DP2MH132938-01S1	Assessing Internalized Health-Related Stigma in Spanish-Speaking Latino Adults	University Of Florida	3/21/25
F31AA030722	Examining differential effects of state equality-promoting policies on harmful alcohol use among sexual and gender minority adults in the U.S.: an econometrics approach for causal inference	University Of California, San Francisco	3/21/25
F31CA271474	Low Dose Computed Tomography (LDCT) Eligibility and Outcome differences between Sexual and Gender Minorities and their Sexual and Gender Majority Counterparts	University Of Michigan At Ann Arbor	3/21/25
F31DA059345	Minority Stress, Stimulant Use, and HIV among Sexual Minority Men: A Biopsychosocial Approach	San Diego State University	3/21/25
F31MH132187	Applying Computational Phenotypes To Assess Mental Health Disorders Among Transgender Patients in the United States	Univ Of North Carolina Chapel Hill	3/21/25
F31MH133472	Identifying preferences for receiving HIV prevention services among GBMSMs and for providing HIV prevention services among HCPs who are active-duty service members	Florida International University	3/21/25
F31MH135787	Extending the Prevention Toolbox: Exploring the Acceptability and Impact of Long-acting Injectable PrEP among MSM in Baltimore: A Pilot Study	Johns Hopkins University	3/21/25
F31MH135828	Employment as prevention: Adapting a structural intervention to achieve HIV equity among immigrant Latino MSM.	University Of Miami School Of Medicine	3/21/25
F31NR020760	Interpersonal Protective Factors and Mental Health Symptom Self-Management Among Black Transgender Women: A Mixed-Methods Study	Johns Hopkins University	3/21/25
F32AA030194	Sexual orientation, gender identity, and alcohol use: A multi-method analysis of developmental differences and key mechanisms	Univ Of Maryland, College Park	3/21/25
F32MD017452	Sexual Minority Mental Health During the COVID-19 Pandemic: An Intersectional, Social Epidemiologic Investigation	Boston Children's Hospital	3/21/25
G13LM013533	The Use of Diversity: Managing Race and Representation in Law, Politics, and the Biosciences	Northeastern University	3/21/25
K01HL151902	Building methods to assess and address cardiovascular health in transgender adults	Boston Medical Center	3/21/25
K01HL151902-04S1	Assessing the burden of dementia in transgender populations	Boston Medical Center	3/21/25
K01MH116737-06S1	COVID-19 Administrative Supplement to K01: Adapting, Pilot Testing a Behavioral Intervention to Incorporate Advances in HIV Prevention for Black Young MSM in Alabama	Florida State University	3/21/25
K01MH117142-05S1	Biological Mechanisms of Suicidal Behavior among Sexual Minority Adolescents - Supplement	University Of Pittsburgh At Pittsburgh	3/21/25
K01MH130270	Intersectional minority stress, mental health, and HIV treatment and care among MSM living with HIV in Ghana	State University Of New York At Buffalo	3/21/25
K01MH134764	Intersectional discrimination and linkage to HIV prevention and care in transgender women in Ecuador	Whitman-Walker Institute, Inc.	3/21/25
K08CA276706	Understanding Breast Cancer Risk and Screening in Transgender Persons through a Pilot Breast Cancer Screening Program	Medical College Of Wisconsin	3/21/25
K08MD019314	Predicting acute and dynamic suicide risk in rural sexual minorities	University Of Oregon	3/21/25
K12AR084217-09S1	Supporting the Tufts BIRCWH Program with an Additional Scholar Position	Tufts University Boston	3/21/25

K12AR084219-26S1	UCSF-Kaiser Department of Research Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program	University Of California, San Francisco	3/21/25
K12AR084220-21S1	Building Interdisciplinary Research Careers in Women's Health at UC Davis	University Of California At Davis	3/21/25
K12HD000850	Pediatric Scientist Development Program	Weill Medical Coll Of Cornell Univ	3/21/25
K12HD103084	Stanford Women's Reproductive Health Research Career Development Program	Stanford University	3/21/25
K99MD019060	A digital health intervention to increase condom use among adolescent sexual minority males	Trustees Of Indiana University	3/21/25
P01HD109850	A longitudinal study investigating TDM and adolescent health and development: Brain, Behavior and well-Being	University Of Wisconsin-Madison	3/21/25
P20GM135007	Vermont Center for Cardiovascular and Brain Health	University Of Vermont & St Agric College	3/21/25
P30CA016056-47S1	Two-Spirit Films in Indigenous Cancer Health	Roswell Park Cancer Institute Corp	3/21/25
P50MD017349	Chicago Chronic Condition Equity Network (C3EN)	University Of Chicago	3/21/25
P50MD017349-03S1	Chicago Chronic Condition Equity Network (C3EN)	University Of Chicago	3/21/25
P50MH126283	ALACRITY for Early Screening and Treatment of High Risk Youth (eSToRY)	Cambridge Health Alliance	3/21/25
R00AA028049	A mixed-methods approach to understanding stress and hazardous drinking among same-sex female couples	Northwestern University At Chicago	3/21/25
R00AA030079	Event-level Antecedents of Heavy Drinking Among Bisexual and Heterosexual Women with and without Histories of Sexual Assault	Rhode Island Hospital	3/21/25
R00AA030601	Stigma,Romantic Relationships, and Alcohol Use Among Transgender and Nonbinary Young Adults	Boston University Medical Campus	3/21/25
R00CA260718	Testing the effect of anti-tobacco message framing on polytobacco use in lesbian, gay, bisexual, and transgender young adults	Ohio State University	3/21/25
R00DA055508	A Gender-Affirming Stigma Intervention to Improve Substance Misuse and HIV Risk among Transgender Women	Illinois Institute Of Technology	3/21/25
R00MD015770	Population-Specific Eating Disorder Risk Factors in Sexual Minority Women	University Of Colorado Denver	3/21/25
R00MD017967	Sexually Transmited Infection Testing Risk and Prevention among Trans Women (STRiP-T)	University Of Central Florida	3/21/25
R01AA027248	Alcohol, minority stress, and intimate partner violence: Temporal and prospective associations in sexual minority young adults	University Of Wisconsin Milwaukee	3/21/25
R01AA027252	Stress, hazardous drinking and intimate partner aggression in a diverse sample of women and their partners	Columbia University Health Sciences	3/21/25
R01AA028810	Peer Victimization and Risky Alcohol Use among Sexual Minority Youth: Understanding Mechanisms and Contexts	State University Of New York At Buffalo	3/21/25
R01AA029044	Intersectional Approaches to Population-Level Health Research: Role of HIV Risk and Mental Health in Alcohol Use Disparities among Diverse Sexual Minority Youth	Northwestern University At Chicago	3/21/25
R01AA029044-04S1	Intersectional Approaches to Population-Level Health Research: Role of HIV Risk and Mental Health in Alcohol Use Disparities among Diverse Sexual Minority Youth	Northwestern University At Chicago	3/21/25
R01AA029076	Project Recognize: Improving Measurement of Alcohol Use and Other Disparities by Sex, Sexual Orientation, and Gender Identity through Community Engagement	Northwestern University At Chicago	3/21/25
R01AA029076-04S1	Improving Measurement of Alcohol Use and Other Disparities by Sex, Sexual Orientation, and Gender Identity through Community Engagement	Northwestern University At Chicago	3/21/25
R01AA029088	A unified protocol to address sexual minority women's minority stress, mental health and hazardous drinking	Yale University	3/21/25
R01AA029989	Long-term and Daily Associations among Intersectional Minority Stress, Structural Oppression, and Alcohol Use and Misuse among Sexual Minority Adolescents of Color	Univ Of Maryland, College Park	3/21/25
R01AA030017	A Randomized Controlled Trial of a Game-Based Intervention to Reduce Alcohol Use among Sexual and Gender Minority Youth	University Of Pittsburgh At Pittsburgh	3/21/25
R01AA030243	Sexual Fluidity and Longitudinal Changes in Alcohol Misuse and Associated Health Consequences	University Of Michigan At Ann Arbor	3/21/25
R01AA030558	Experiences of Rural Sexual and Gender Minority Couples: Does Alcohol Use Explain the Link Between Minority Stress and Intimate Partner Discord and Violence	University Of Nebraska Lincoln	3/21/25
R01AA031175	Feasibility and Effectiveness of Gamified Digital Intervention to Prevent Alcohol and Mental Health Risks	Loyola Marymount University	3/21/25
R01AA031213	The Impact of Minority Stress on Alcohol-Related Sexual Assault among Sexual Minority College Students: An Intersectional, Mixed-Methodological Study	University Of Wisconsin Milwaukee	3/21/25
R01AG060944	The All-or-Nothing Marriage? Marital Functioning and Health Among Individuals in Same and Different-Gender Marriages	University Of Minnesota	3/21/25
R01AG063954	Establishing the science behind Alzheimer's recruitment registries: opportunities for increasing diversity and accelerating enrollment into trials	Banner Health	3/21/25
R01AG069003	Looking Back to Look Forward: Social Environment Across the Life Course, Epigenetics, and Birth Outcomes in Black Families	Univ Of North Carolina Chapel Hill	3/21/25

R01AG069041	Social Convoys, Cognitive Reserve and Resilience, and Risk for Alzheimer's Disease and Related Dementias	New York State Psychiatric Institute Dba Research Foundation For Mental Hygiene, Inc	3/21/25
R01AG070059	Sampling Strategies and Measure Development for the LGBT Aging Project (SAMLAP)	National Opinion Research Center	3/21/25
R01AG072592	Cerebral small vessel disease burden and racial disparity in vascular cognitive impairment and Alzheimer,Ãôs disease and its related dementias	University Of Cincinnati	3/21/25
R01AG073440	Examining Health Comorbidities and Healthcare Utilization Disparities among Older Transgender and Cisgender Adults in the U.S.	Brown University	3/21/25
R01AG075734-03S1	Training the Long-Term Services and Supports Dementia Care Workforce in Provision of Care to Sexual and Gender Minority Residents	University Of Minnesota	3/21/25
R01AG077934	Structural Racism and Discrimination in Older Men's Health Inequities	University Of California, San Francisco	3/21/25
R01AG082080	Improving Inclusivity of Alzheimer,Ãôs Disease and Related Dementias Research for Asian Americans and Latinx through Nationally Representative Hybrid Sampling.	University Of Michigan At Ann Arbor	3/21/25
R01AG083177	Enhancing Measurement and Characterization of Roles and Experiences of Sexual and Gender Minority Caregivers of Persons living with Alzheimer's Disease and Related Dementias	University Of Nevada Las Vegas	3/21/25
R01AG087121	ADRD risk and resilience among Black Americans: A 20-year longitudinal study	University Of Michigan At Ann Arbor	3/21/25
R01AI169636-03S1	ED2PrEP - patient focused, low-burden strategies for PrEP uptake among emergency departments patients: a cross-over hybrid implementation-effectiveness trial	Albert Einstein College Of Medicine	3/21/25
R01CA276594-02S1	Randomized Controlled Trial of Dyadic Financial Incentive Treatment for Dual Smoker Couples: Evaluation of Efficacy, Mechanisms, and Cost Effectiveness	University Of Oklahoma Hlth Sciences Ctr	3/21/25
R01DA056235	Structural Influences on Methamphetamine Use among Black Gay and Bisexual Men in Atlanta	Emory University	3/21/25
R01DA056287	Comparative- and cost-effectiveness research determining the optimal intervention for advancing transgender women living with HIV to full viral suppression	Friends Research Institute, Inc.	3/21/25
R01DA059022	The Collaborative Care PrTNER (Prevention, Treatment, Navigation,Engagement, Resource) Project	Children's Hosp Of Philadelphia	3/21/25
R01DA059480	Elucidating minority stress influences on tobacco use at the intersection of sexual orientation and rurality	University Of Oklahoma Hlth Sciences Ctr	3/21/25
R01DK130864-03S1	The role of circulating meta-inflammatory monocytes in adolescent insulin resistance	University Of Michigan At Ann Arbor	3/21/25
R01GM155395	Promoting Inclusive Excellence	University Of Pittsburgh At Pittsburgh	3/21/25
R01HD109320	Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality	Ibis Reproductive Health	3/21/25
R01HD109320-02S1	Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality	Ibis Reproductive Health	3/21/25
R01HD111516	Intervention to improve parent communication about sexuality with sexual minority male adolescents	University Of Pennsylvania	3/21/25
R01HD112464	Health and economic consequences of changing federal and state policies on reproductive health.	University Of California, San Francisco	3/21/25
R01HD115551	Understanding multilevel predictors affecting family formation among sexual and gender minority couples	Northwestern University At Chicago	3/21/25
R01HD115921	The effects of gender-affirming sex steroids on brain development in adolescents	Boston Children's Hospital	3/21/25
R01HL169503	Geographically-Explicit Ecological Momentary Assessment Protocol to Assess the Linkages Between Intersectional Discrimination and CVD Risk Among Sexual and Gender Minorities	New York University	3/21/25
R01HL177518	Cardiometabolic Impact of Gender-Affirming Hormone Therapy in Transmasculine Young Adults	Medical College Of Wisconsin	3/21/25
R01MD013907-05S1	A culturally centered CBT protocol for suicidal ideation and suicide attempts among Latinx youth	Emma Pendleton Bradley Hospital	3/21/25
R01MD015256	Sexual orientation-related disparities in obstetrical and perinatal health	Harvard Pilgrim Health Care, Inc.	3/21/25
R01MD015256-05S1	Improving service delivery models of medically assisted reproduction: A patient journey mapping study of sexual minority women couples' experience of medicalized family formation	Harvard Pilgrim Health Care, Inc.	3/21/25
R01MD015722	Adolescent health at the intersections of sexual, gender, racial/ethnic, immigrant identities and native language	University Of Minnesota	3/21/25
R01MD017085	Social Connectedness and Health among Gender Minority People of Color	Columbia University Health Sciences	3/21/25
R01MD017573	Sexual Assault Recovery Among Sexual Minority Women: A Longitudinal, Multi-Level Study	University Of Washington	3/21/25
R01MD017588	Promoting Health and Reducing Risk among Hispanic Sexual Minority Youth and their Families	University Of Miami Coral Gables	3/21/25
R01MD018582	Psychosocial Predictors of Risk for Suicidal Behavior Among Gender Minority Adolescents	University Of Pittsburgh At Pittsburgh	3/21/25
R01MD019029	Assessing intersectional, multilevel and multidimensional structural racism for English- and Spanish-speaking populations in the US	University Of Maryland Baltimore	3/21/25

R01MD019029-02S1	Assessing intersectional, multilevel and multidimensional structural racism for English- and Spanish-speaking populations in the US	University Of Maryland Baltimore	3/21/25
R01MH127014-03S1	Dopamine Availability and Developmental Pathways of Adolescent Depression and Anhedonia - Administrative Supplement	University Of Pittsburgh At Pittsburgh	3/21/25
R01MH129175	Strategies to Prevent HIV Acquisition Among Transgender MSM in the US	University Of Michigan At Ann Arbor	3/21/25
R01MH129285	A multi-level approach to improve HIV prevention and care for transgender women of color	New York State Psychiatric Institute Dba Research Foundation For Mental Hygiene, Inc	3/21/25
R01MH130208	Choice-Based PrEP Delivery for Transgender People in Uganda	Infectious Diseases Institute	3/21/25
R01MH130375	A longitudinal and experience sampling investigation of rejection sensitivity and its role in sexual minority adolescents' mental health	Rosalind Franklin Univ Of Medicine & Sci	3/21/25
R01MH130675	1/4 Asian Bipolar Genetics Network (A-BIG-NET)	Broad Institute, Inc.	3/21/25
R01MH133543	Implementing sustainable evidence-based mental healthcare in low-resource community settings nationwide to advance mental health equity for sexual and gender minority individuals	Yale University	3/21/25
R01MH134051	A Strengths-Based, Intersectional Approach to Suicide Prevention Among Black Sexual and Gender Minority Youth	University Of Central Florida	3/21/25
R01MH134176-02S1	Effect of Medicaid Accountable Care Organizations on Behavioral Health Care Quality and Outcomes for Children	University Of Massachusetts Amherst	3/21/25
R01MH134264	Implementation of PrEP Care Among Women in Family Planning Clinics	Rush University Medical Center	3/21/25
R01MH134267	Evaluating the effectiveness of a mobile HIV prevention app to increase HIV and STI testing and PrEP initiation among rural men who have sex with men	Emory University	3/21/25
R01MH134721	A randomized clinical trial of client-centered care coordination to improve pre-exposure prophylaxis use for Black men who have sex with men	University Of Maryland Baltimore	3/21/25
R01MH135498	Using digital photovoice to explore the relationships between social media content and suicidality among transgender adolescents	University Of Wisconsin Milwaukee	3/21/25
R01MH138225	A Multi-Level Integrated Strategy to Optimize PrEP Adherence for Black MSM and Accelerate Implementation at Scale	Yale University	3/21/25
R01NR020309	Harnessing the power of technology to develop a population-based HIV prevention program for trans girls	Center For Innovative Public Health Research	3/21/25
R01NR020437	Characterizing intersecting sexual, gender, and race-based stigmas affecting communities of US transgender women and cisgender men who are sexually active with men	Johns Hopkins University	3/21/25
R01NR021019	Enhancing Structural Competency in School-Based Health Centers to Address LGBTQ+ Adolescent Health Equity	Pacific Institute For Res And Evaluation	3/21/25
R01NR021170	Status-neutral community-based multilevel intervention to address intersectional stigma and discrimination, and increase HIV testing, PrEP, and ART uptake among YGBMSM in Ghanaian Slums	University Of Rochester	3/21/25
R01NS101483	Reducing Disparities in Dementia and VCID Outcomes in a Multicultural Rural Population	University Of Miami School Of Medicine	3/21/25
R01TW012392	Buddhism and HIV Stigma in Thailand: An Intervention Study	University Of California Los Angeles	3/21/25
R01TW012392-03S1	Buddhism and HIV Stigma in Thailand: An Intervention Study	University Of California Los Angeles	3/21/25
R01TW012671	Adaptation and feasibility of Many Men Many Voices (3MV), an HIV prevention intervention to reduce intersectional stigma and increase HIVST among YSMM residing in Ghanaian slums	University Of Rochester	3/21/25
R03DA052651	Improving Sexual Minority Health: Differences in Substance Use, Substance Use Treatment, and Associated Chronic Diseases among Rural versus Urban Populations	Ohio State University	3/21/25
R03MH130275	Applying Deep Learning for Predicting Retention in PrEP Care and Effective PrEP Use among Key Populations at Risk for HIV in Thailand	Univ Of Massachusetts Med Sch Worcester	3/21/25
R13AA031402	Enhancing dissemination and career development in sex and gender translational science in alcohol use	Yale University	3/21/25
R13AG056135	Organization for the Study of Sex Differences Annual Meeting	University Of California Los Angeles	3/21/25
R13AG066389	The ADAR Summit Meeting	University Of South Carolina At Columbia	3/21/25
R13HD090968	Boston University Conference on Language Development, 2022-2026	Boston University (Charles River Campus)	3/21/25
R13HL173969	Society of Behavioral Medicine 2024 Annual Meeting & Scientific Sessions	Society Of Behavioral Medicine	3/21/25
R13MD019531	SOCIAL MEDICINE CASES FOR HEALTH EQUITY	University Of California Berkeley	3/21/25
R21AG087792	Bridge to Belonging (B2B): Peer led intervention to reduce loneliness and depression among older gay and bisexual men	Fenway Community Health Center	3/21/25
R21AI178840	Defining the neovaginal microbiome after gender affirming vaginoplasty	Case Western Reserve University	3/21/25
R21AI183907	Applying a Behavioral Economic Approach on PrEP and Hormone Options among Transgender Women	University Of Washington	3/21/25
R21CA292185	Adapting and testing a smoking cessation intervention for transgender and gender-diverse individuals	Massachusetts General Hospital	3/21/25
R21DA053156	Social environmental drivers of stimulant use and its impact on HIV prevention and treatment in Black men who have sex with men	New York State Psychiatric Institute Dba Research Foundation For Mental Hygiene, Inc	3/21/25

R21DA058575	Tailoring Delivery of Long Acting PrEP for Cisgender (MSM) who Use Methamphetamine	Harvard Pilgrim Health Care, Inc.	3/21/25
R21DA060856	CHAMPION - Combining HIV And Stimulant Prevention and Treatment Interventions Optimized for HIV-Negative MSM	University Of California, San Diego	3/21/25
R21DA062591	Optimizing long-acting injectable PrEP strategies for sexual minority men who use methamphetamine	Graduate School Of Public Health And Health Policy	3/21/25
R21DC021537	Improving the accessibility of transgender voice training with visual-acoustic biofeedback	University Of Cincinnati	3/21/25
R21HD107609	Cardiometabolic effects of gender-affirming hormone therapy in transgender adolescents	Yale University	3/21/25
R21HD110617	Development and Initial Trial of Brief Interventions to Help Parents of Stigmatized Youth Reduce Distress and Strengthen Attachment	Yale University	3/21/25
R21HD114341	Understanding the Complex Reproductive Health Needs of Formerly Incarcerated Young Men	Johns Hopkins University	3/21/25
R21HD115838	Feasibility study for assessing processes and outcomes related to gender affirming care	University Of Colorado Denver	3/21/25
R21HD116080	Confidentiality in use of health insurance coverage for reproductive health services	Brigham And Women's Hospital	3/21/25
R21MD018707	Identifying Community-Informed DoxyPEP Implementation Strategies to Guide Equitable Delivery of Syphilis Prevention	University Of Chicago	3/21/25
R21MD019089	Advancing help-seeking and recovery measures for sexual and gender minority survivors of gender-based violence	Temple Univ Of The Commonwealth	3/21/25
R21MD019345	Ecological momentary assessment of daily minority stressors and cannabis and tobacco co-use among sexual minority young adults	University Of Oklahoma Hlth Sciences Ctr	3/21/25
R21MD019829	The Roles of Parental Mental Health and Help-Seeking: Utilizing a Family Systems Approach to Upstream Suicide Prevention for Sexual Minority Youth	University Of Southern California	3/21/25
R21MH128114	Strengthening the HIV care continuum for transgender women living with HIV in Malaysia	Yale University	3/21/25
R21MH129186	Expanding "Safe Spaces 4 Sexual Health," a Mobile Van HIV/STI Testing and Care Linkage Strategy, for Black MSM in online spaces	Johns Hopkins University	3/21/25
R21MH130217	In-depth Understanding of HIV Risk Behavior among Men Who Have Sex With Men in Sub-Saharan Africa: Secondary Analysis of HPTN 075 Data	New York State Psychiatric Institute Dba Research Foundation For Mental Hygiene, Inc	3/21/25
R21MH130302	The Influence of Developmental Assets on Intersectional Stigma and HIV Prevention Behaviors in Black MSM	Ohio State University	3/21/25
R21MH132421	Formative work to develop differentiated communication tools to facilitate transgender women's recruitment, enrollment, and retention in HIV vaccine trials	University Of Colorado Denver	3/21/25
R21MH133487	Enhancing Engagement with Online Health Messaging about Oral and Injectable PrEP Among Young-Adult MSM	Pennsylvania State University, The	3/21/25
R21MH135130	Cultural Consensus Modeling to Identify Culturally Relevant Risk and Protective Factors for Suicide among Sexual Minority Youth	Louisiana State Univ A&M Col Baton Rouge	3/21/25
R21MH135234	Design of a Lay Health Worker Training Intervention to Promote Mental Health Care Access for Racially Diverse Transgender Youth	University Of California Santa Barbara	3/21/25
R21MH135779	Formative work for the development of an intervention to support combined HIV/syphilis self-testing and linkage to prevention and treatment services for transgender women in South Africa	University Of Colorado Denver	3/21/25
R21MH136855	Over-the-Counter PrEP: Acceptability, Feasibility, and Potential Impact of Access without a Prescription (OFFSCRIPT)	Harvard Pilgrim Health Care, Inc.	3/21/25
R21MH136915	Impact of geographic mobility on PrEP and HIV care outcomes among Latino gay, bisexual and other men who have sex with men	New York Blood Center	3/21/25
R21TW012010	Stigma Reduction and Gender Affirmation to Promote HIV Prevention/Testing in Trans Women	Emory University	3/21/25
R24AG065151	Recruiting & Retaining Older African Americans into Research (ROAR)	University Of Michigan At Ann Arbor	3/21/25
R24AG066599	Building Community and Research Engagement among Sexual and Gender Minority Older Adults at Risk for Alzheimer,Āōs Disease and Related Dementias	Emory University	3/21/25
R24NS132283	PURPOSE: Positively Uniting Researchers of Pain to Opine, Synthesize, and Engage	Neurovations	3/21/25
R24NS132283-01S1	PURPOSE: Positively Uniting Researchers of Pain to Opine, Synthesize, and Engage	Neurovations	3/21/25
R25AG076390	A Multidimensional Aging Science Program: MSTEM Scholars Trained in Aging Research (MSTEM STAR)	California State University Fullerton	3/21/25
R25CA265802	Sexual and Gender Minority Cancer Curricular Advances for Research and Education (SGM Cancer CARE)	University Of Tx Md Anderson Can Ctr	3/21/25
R25EB034489	ESTEEMED Scholars Program at the University of Rhode Island	University Of Rhode Island	3/21/25
R25GM050070	BioPREP: Biology Partnership in Research and Education Program	State University New York Stony Brook	3/21/25
R25GM060566	The Next Generation of Black Women Scientists	Spelman College	3/21/25
R25GM066534	Virginia Tech Postbaccalaureate Research Education Program (VT PREP)	Virginia Polytechnic Inst And St Univ	3/21/25
R25GM144253	Intermountain PREP	University Of Utah	3/21/25

R25GM147291	STEM-Coaching and Resources for Entrepreneurial Women (CREW)	Medical University Of South Carolina	3/21/25
R25GM152359	PREP-MT: Providing Research Education for Postbaccalaureate Trainees in Montana	Montana State University - Bozeman	3/21/25
R25HD116367	Restoring equity to measuring and preventing perinatal intimate partner violence (Remap-IPV)	Univ Of North Carolina Chapel Hill	3/21/25
R25HG012330	Training in Genomics Research (TiGeR)	Arizona State University-Tempe Campus	3/21/25
R25MH119858	SHINE Strong: Building the pipeline of HIV behavioral scientists with expertise in trans population health	Public Health Foundation Enterprises	3/21/25
R25MH126703	Pipeline to Graduate Education and Careers in Behavioral and Social Science Research for URM Undergraduates: Addressing HIV in Sexual and Gender Minority Communities	University Of Michigan At Ann Arbor	3/21/25
R25MH129290	Short Trainings on Methods for Recruiting, Sampling, and Counting Hard-to-Reach Populations: The H2R Training Program	University Of California, San Francisco	3/21/25
R33HD107988	Optimizing an mHealth intervention to improve uptake and adherence of the HIV pre-exposure prophylaxis (PrEP) in vulnerable adolescents and emerging adults	Univ Of Massachusetts Med Sch Worcester	3/21/25
R33MH120236	Suicide Prevention for Sexual and Gender Minority Youth	San Diego State University	3/21/25
R33TW011665	Development and Testing of a Mobile Application to Enhance HIV Prevention Cascade in Malaysian MSM	University Of Connecticut Storrs	3/21/25
R34AA030035	Integrated Alcohol and Sexual Assault Prevention for Bisexual Women	Rhode Island Hospital	3/21/25
R34AA030662	An Online Family-based Program to Prevent Alcohol Use and Dating and Sexual Violence among Sexual and Gender Minority Youth	University Of Colorado	3/21/25
R34CA283408	Adapting the FOCUS Program for Sexual and Gender Minority (SGM) Cancer Patients and Caregivers	University Of Rochester	3/21/25
R34DA055503	Integration of Electronic SBI(RT) into an HIV Testing Program to Reduce Substance Use and HIV risk Behavior among MSM in Argentina	Florida State University	3/21/25
R34DA058191	Proud to Quit (P2Q): A Person-centered mobile technology intervention for smoking cessation among transgender adults	University Of Colorado Denver	3/21/25
R34MH124081	Adapting effective mhealth interventions to improve uptake and adherence of the HIV pre- exposure prophylaxis (PrEP) in Thai young MSM	Univ Of Massachusetts Med Sch Worcester	3/21/25
R34MH126894	Making universal, free-of-charge antiretroviral therapy work for sexual and gender minority youth in Brazil	Brown University	3/21/25
R34MH129187	Brothers building brothers by breaking barriers (B6): A resilience-focused intervention for young Black gay and bisexual men living with HIV	Emory University	3/21/25
R34MH129189	Data-driven, peer-led messaging using social media influencers to increase PrEP awareness and uptake among transgender women	Temple Univ Of The Commonwealth	3/21/25
R34MH129208	3T-Prevent: Piloting a multi-level, combination intervention strategy to expand HIV and bacterial STI prevention	Medical College Of Wisconsin	3/21/25
R34MH129218	Piloting a multi-level intervention to promote viral suppression among transgender women living with HIV	Univ Of North Carolina Chapel Hill	3/21/25
R34MH129279	eSTEP: An integrated mHealth intervention to engage high-risk individuals along the full PrEP care continuum	San Diego State University	3/21/25
R34MH129782	CA-LINC: A Culturally Adapted Care Coordination Suicide Detection and Intervention Model for Black Youth	University Of North Carolina Charlotte	3/21/25
R34MH129785	The BH-Works Suicide Prevention Program for Sexual and Gender Minority Youth	Virginia Polytechnic Inst And St Univ	3/21/25
R34MH132405	MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women	Public Health Foundation Enterprises	3/21/25
R34MH133768	Development and Preliminary Trial of a Digital Transdiagnostic CBT Intervention for Transgender Adolescents	Lurie Children's Hospital Of Chicago	3/21/25
R34MH134603	Feasibility, acceptability, and preliminary efficacy of an adapted group-based and online HIV prevention intervention for immigrant sexual minority men in the US	University Of Illinois At Chicago	3/21/25
R34MH134912	Youth Empowerment and Safety Intervention for Systems-involved Sexual and Gender Minority Youth at Risk of Suicide	Case Western Reserve University	3/21/25
R34MH137753	Developing and pilot testing an eHealth decision support tool for young trans women to improve informed decision making about PrEP	Temple Univ Of The Commonwealth	3/21/25
R36AG083386	Multi-Level Determinants of Sexual and Gender Minority Aging	Vanderbilt University	3/21/25
R36DA058563	Exploring the Role of Novel Aging-Focused Syndemic Conditions on HIV Risk and Quality of Life among HIV-Negative Older Sexual Minority Men	University Of Miami Coral Gables	3/21/25
R36DA058819	Identifying Transdiagnostic Intervention Targets for PTSD-SUD Comorbidity in a Vulnerable Population: A Mixed-Method Study	Hunter College	3/21/25
R37AG076057	How Spouses Influence Each Other's Health in Same- and Different-Sex Marriages: A Dyadic and Longitudinal Assessment from Mid to Later Life	University Of Texas At Austin	3/21/25
R37CA226682	A Randomized Controlled Trial of an HPV Vaccine Intervention for Young Sexual Minority Men	Ohio State University	3/21/25
R43MD019197	Bridges: A digital intervention to increase workplace belonging	Pro-Change Behavior Systems, Inc.	3/21/25
R44AG045011	Phase IIB: Development of TruT Algorithm for Commercialization in Androgen Disorders	Function Promoting Therapies, Llc	3/21/25
R44HD103517	Step UP for STEM and Health Careers: An Intervention to Reduce STEM-related biases and improve high school STEM learning environments	Resilient Games Studio, Llc	3/21/25

R44HD106855	Evidence-based Parent Training for Diverse Families (PTDF)	Iris Media, Inc.	3/21/25
R56AG079510	Asian Americans & Racism: Individual and Structural Experiences (ARISE)	University Of California, San Francisco	3/21/25
R56AG087032	Social Connectedness, Loneliness, and Health Among Aging Black Sexual Minority Men	Rand Corporation	3/21/25
R56HD113725	Examining reproductive and sexual health during the transition to adulthood	Innovation Research And Training, Inc.	3/21/25
R61DA056779	Cue Reactivity Modulation in MSM with Methamphetamine Use Disorder	Icahn School Of Medicine At Mount Sinai	3/21/25
R61MH133710	Targeting Minority Stressors to Improve Eating Disorder Symptoms in Sexual Minority Individuals with Eating Disorders	Auburn University At Auburn	3/21/25
S21MD012472	Texas Minority Health, Research and Outreach (MiHERO)	University Of North Texas Hlth Sci Ctr	3/21/25
S21MD018960	Charles R. Drew University of Medicine and Science Research Endowment Program	Charles R. Drew University Of Med & Sci	3/21/25
SC1DA052120	GHB Toxicokinetics: Role of sex hormone dependent monocarboxylate transporter regulation and potential for altered overdose risk in transgender men and women	University Of The Pacific-Stockton	3/21/25
T32DA057926	Building an interprofessional and diverse workforce in substance use and pain	University Of Pittsburgh At Pittsburgh	3/21/25
T32MD019780	ADVANCE SGM Health for Research Diversity	University Of Alabama At Birmingham	3/21/25
T34GM149823	U-RISE at Spelman College	Spelman College	3/21/25
T37MD008636	Transdisciplinary Health Disparities Research Training for Native Hawaiians and Pacific Students	University Of Hawaii At Manoa	3/21/25
U01AI156874	Effectiveness of Relationship Education for Reducing HIV Incidence in Men Who Have Sex with Men	Northwestern University At Chicago	3/21/25
U01DA036926	Using Longitudinal Research to Engage African American and Latinx Sexual- and Gender-Minority Youth in the HIV Prevention and Care Continua and Reduce HIV/AIDS-Related Disparities	Children's Hospital Of Los Angeles	3/21/25
U01DA036939	Multilevel Influences on HIV and Substance Use in a YMSM cohort	Northwestern University At Chicago	3/21/25
U01GM132133-05S1	Building Up	University Of Pittsburgh At Pittsburgh	3/21/25
U01GM132133-05S2	Building Up	University Of Pittsburgh At Pittsburgh	3/21/25
U01GM132375	Boosting Mentor Effectiveness iN Training of Research Scientists (MENTORS) Using Social Cognitive Career Theory to Support Entry of Women & Minorities into Physician-Scientist Careers	University Of Chicago	3/21/25
U01HD108738	Harnessing the power of text messaging to reduce HIV incidence in adolescent males across the United States	Center For Innovative Public Health Research	3/21/25
U01MD018310	Faithful Response II: COVID-19 Rapid Test-to-Treat with African American Churches	University Of Missouri Kansas City	3/21/25
U01MD019398	Increasing financial and health equity among low income black youth and young adults	University Of California, San Francisco	3/21/25
U01MD019398-03S1	Increasing financial and health equity among low income black youth and young adults - DEIA Supplement	University Of California, San Francisco	3/21/25
U01MH136574	Hermanos de Luna y Sol: A community-based HIV prevention intervention	San Francisco State University	3/21/25
U19NS120384	The Clinical Significance of Incidental White Matter Lesions on MRI Amongst a Diverse Population with Cognitive Complaints (INDEED)	University Of California At Davis	3/21/25
U24AG083253	Resource Centers for Minority Aging Research National Coordinating Center (RCMARs NCC)	Gerontological Society Of America	3/21/25
U24DK138889	VCU National Coordinating Center for Advancing Gender Inclusive Excellence	Virginia Commonwealth University	3/21/25
U24MD017250	Research Coordinating Center to Reduce Disparities in Multiple Chronic Diseases (RCC RD-MCD)	University Of California, San Francisco	3/21/25
U24MD017250-04S1	Research Coordinating Center to Reduce Disparities in Multiple Chronic Diseases (RCC RD-MCD)	University Of California, San Francisco	3/21/25
U54CA267735	Catalyzing Systemic Change at Drexel University to Support Diverse Faculty in Health Disparities Research	Drexel University	3/21/25
U54CA280915	Vanderbilt FIRST - Elevating Excellence and Transforming Institutional Culture	Vanderbilt University Medical Center	3/21/25
U54DA060049	Advancing Tobacco Regulatory Science to Reduce Health Disparities	Univ Of North Carolina Chapel Hill	3/21/25
U54HD113292	Center to Advance Reproductive Justice and Behavioral Health among Black Pregnant/Postpartum Women and Birthing People (CORAL).	Morehouse School Of Medicine	3/21/25
U54MD007582	FAMU Center for Health Disparities Research	Florida Agricultural And Mechanical Univ	3/21/25
U54MD007586	The RCMI Program in Health Disparities Research at Meharry Medical College	Meharry Medical College	3/21/25
U54MD007598	Center for Accelerating Excellence in Translational Science (AXIS)	Charles R. Drew University Of Med & Sci	3/21/25
U54MD007601-38S2	Evaluating HPV Vaccination Uptake Barriers and its Efficacy in PLWH	University Of Hawaii At Manoa	3/21/25
U54MD012393	The FIU Research Center in a Minority Institution (FIU-RCMI)	Florida International University	3/21/25
U54MD012523	Center for Health Equity Research (CHER)	University Of Illinois At Chicago	3/21/25
UG1HD113160	Intensive Combination Approach to Rollback the HIV Epidemic in Nigerian Youth (iCARE) Plus Effectiveness / Implementation Hybrid Study	Northwestern University At Chicago	3/21/25

UG1HD113162	Resilient HIV Implementation Science with Sexual and Gender Minority Youths using Evidence (RISE) Clinical Research Center	University Of Maryland Baltimore	3/21/25
UG3AI169631	Keeping it LITE 2: Exploring HIV Risk in Vulnerable Youth with Limited Interaction and Digital Health Intervention (LITE-2)	Hektoen Institute For Medical Research	3/21/25
UG3AI176853	Limited interaction cohort to identify determinants of viral suppression in MSM and transfeminine individuals living with HIV: A multilevel approach	Emory University	3/21/25
UG3HD115253	Adaptable Community-Engaged Intervention for Violence Prevention: Michigan Model	Eastern Michigan University	3/21/25
UG3MH133258	Identifying socioecological profiles that impact changes in care outcomes among Black Sexual minority men living with HIV	George Washington University	3/21/25
UG4LM013725	NNLM Region 5: Reaching More People in More Ways	University Of Washington	3/21/25
UH3AI169631	Keeping it LITE 2: Exploring HIV Risk in Vulnerable Youth with Limited Interaction and Digital Health Intervention (LITE-2)	University Of Illinois At Chicago	3/21/25
UH3AI169655	Multilevel strategies to understand and modify the role of structural and environmental context on HIV inequities for sexual and gender minorities of color	George Washington University	3/21/25
UH3AI169658	MyPEEPS Mobile LITE: Limited Interaction Efficacy Trial of MyPEEPS Mobile to Reduce HIV Incidence and Better Understand the Epidemiology of HIV among YMSM	Columbia University Health Sciences	3/21/25
UM1AI068619	HIV Prevention Trials Network Leadership and Operations Center	Family Health International	3/21/25
UM1AI069463	Wits HIV Research Group CLINICAL TRIAL UNIT (CTU) reapplication	Wits Health Consortium (Pty), Ltd	3/21/25
UM1AI154468	ICAP Clinical Trials Unit	Columbia University Health Sciences	3/21/25
UM2HD111076	Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Operations and Collaborations Center (UM2 Clinical Trial Optional)	Westat, Inc.	3/21/25
UM2HD111102	RP4 LEAP	Florida State University	3/21/25
OT2OD035659	Macro-level Health Considerations of Community and Criminal Justice System Relationships in North Texas	Healthy Tarrant County Collaboration	3/22/25
OT2OD035659-01S1	Macro-level Health Considerations of Community and Criminal Justice System Relationships in North Texas	Healthy Tarrant County Collaboration	3/22/25
OT2OD035669	Asian Community-Led Health Equity Structural Intervention (Asian CHESI)	Asian Community Health Coalition	3/22/25
OT2OD035669-01S1	Asian Community-Led Health Equity Structural Intervention (Asian CHESI)	Asian Community Health Coalition	3/22/25
OT2OD035834	Addressing Systemic Barriers Impacting Health in CHC Communities	Asian American Health Coalition/Houston	3/22/25
OT2OD035834-01S1	Addressing Systemic Barriers Impacting Health in CHC Communities	Asian American Health Coalition/Houston	3/22/25
OT2OD035877	Achieving Optimal Sexual and Reproductive Health (SRWH Project)	My Brother's Keeper, Inc.	3/22/25
OT2OD035877-01S1	Achieving Optimal Sexual and Reproductive Health (SRWH Project)	My Brother's Keeper, Inc.	3/22/25
OT2OD035980-01S1	Engaging Diverse Stakeholders in Genomic/Precision Medicine Research: The All of Us Research Program Engagement Core	Vanderbilt University Medical Center	3/22/25
OT2OD036428	All of Us Southern California Consortium (AoUSCC): Engagement, Enrollment, and Retention of Diverse Populations	University Of California-Irvine	3/22/25
OT2OD037655	Building a Diverse Network to Support and Build Pathways for Historically Underrepresented Students in Quantitative-Focused Research Areas Within the All of Us Research Program	New York University	3/22/25
OT2OD037880	NATIONAL LATINO NETWORK (NLN) FOR PRECISION MEDICINE AND HEALTH DISPARITIES RESEARCH	Comprehensive Cancer Center/ Univ/Pr	3/22/25
OT2HL158287-01S6	NHLBI Maternal Morbidity and Mortality (3M) Administrative Coordinating Center	Westat, Inc.	3/24/25
P01AI158571	Design and Development of a Pan-betacoronavirus Vaccine	Duke University	3/24/25
P01AI165072	Discovering Durable Pan-Coronavirus Immunity	Brigham And Women's Hospital	3/24/25
P01AI165077	PanCorVac (Center for Pan-Coronavirus Vaccine Development)	University Of Wisconsin-Madison	3/24/25
P50DA048756-04S3	Prevention Research Center: Parenting Among Women Who Are Opioid Users	University Of Oregon	3/24/25
R01AI153087	Viral and immune kinetics in rhinovirus infection following hematopoietic cell transplantation	Seattle Children's Hospital	3/24/25
R01AI157253	Genetic Analysis of COVID-19 Susceptibility and Resistance Determinants in the Collaborative Cross	Univ Of North Carolina Chapel Hill	3/24/25
R01AI158060	Developing a Multi-epitope Pan-Coronavirus Vaccine	University Of California-Irvine	3/24/25
R01AI158177	Novel delivery platform and antigen design for an effective COVID-19 vaccine	Purdue University	3/24/25
R01AI158463	Coronavirus RNA synthesis by multicomponent protein machines	University Of Wisconsin-Madison	3/24/25
R01AI158775	Development of dual inhibitors targeting the viral main protease and the host cathepsin L as SARS-CoV-2 antivirals	Rutgers Biomedical And Health Sciences	3/24/25
R01AI161374	Development and characterization of engineered therapeutic antibodies against SARS-CoV-2	Washington University	3/24/25
R01AI169543	Rapid response for pandemics: single cell sequencing and deep learning to predict antibody sequences against an emerging antigen	Keck Graduate Inst Of Applied Life Scis	3/24/25
R01AR065493-07S2	Psychosocial Factors and Lupus Disease Progression Among African American Women	Tulane University Of Louisiana	3/24/25

R01DE031927	Development of a handheld rapid air sensing system to monitor and quantify SARS-CoV-2 in aerosols in real-time	Genendeavor, Llc	3/24/25
R01DK122843-05S1	Effect of obesity on HIV pathogenesis, antiretroviral therapy, and metabolic comorbidities	Oregon Health & Science University	3/24/25
R01DK132735	Metabolic and epigenetic reprogramming of vital organs in SARS-CoV-2 induced systemic toxicity	University Of California Los Angeles	3/24/25
R01HL163814	SARS-CoV-2 tropism in the brain and its relationship to COVID-19 pathogenesis	Brigham And Women's Hospital	3/24/25
R01MD016526	Marshallese: Alternate Surveillance for COVID-19 in a Unique Population	Washington State University	3/24/25
R21AI161501	Elucidating Airborne SARS-CoV-2 Infectivity at Single Aerosol Resolution	Univ Of Maryland, College Park	3/24/25
R24AI120942	World Reference Center for Emerging Viruses and Arboviruses (WRCEVA)	University Of Texas Med Br Galveston	3/24/25
R56AI186400	A Tunable Nanophage Platform for Vaccine Development	University Of Colorado Denver	3/24/25
S06GM127983	RAD-X UP NARCH Supplement: A Cherokee Nation Community-Driven Program for Testing and Contact Tracing (Cherokee PROTECT)	Cherokee Nation	3/24/25
S06GM127983	Cherokee Nation Native AmericanResearch Center for Health	Cherokee Nation	3/24/25
U01AI138897-05S2	HOPE in Action: A Clinical Trial of HIV-to-HIV Liver Transplantation	Johns Hopkins University	3/24/25
U01CA260462	Adaptive Immunity and Persistent SARS-CoV-2 Replication	University Of Alabama At Birmingham	3/24/25
U01CA260469	Culturally-targeted communication to promote SARS-CoV-2 antibody testing in saliva: Enabling evaluation of inflammatory pathways in COVID-19 racial disparities	Michigan State University	3/24/25
U01CA260476	Immunologic Signatures of SARS-CoV-2 Vaccination and Disease	Beth Israel Deaconess Medical Center	3/24/25
U01CA260507	Immuno-Serological Assays for Monitoring COVID19 in Patients with Hematologic Malignancies	Yale University	3/24/25
U01CA260508	High-Throughput Dried Blood Spot (HT-DBS) Technologies in SARS COV-2 Serology and Vaccinology	Wadsworth Center	3/24/25
U01CA260513	Pre-exposure Immunologic Health and Linkages to SARS-COV2 Serologic Responses, Endothelial Cell Resilience, and Cardiovascular Complications: Defining the mechanistic basis of high risk endotypes.	Case Western Reserve University	3/24/25
U01CA260513-02S3	Pre-exposure Immunologic Health and Linkages to SARS-COV2 Serologic Responses, Endothelial Cell Resilience, and Cardiovascular Complications: Defining the mechanistic basis of high risk endotypes.	Case Western Reserve University	3/24/25
U01CA260584	SARS-CoV-2 Serological Antibody Testing for Disease Surveillance and Clinical Use	Kaiser Foundation Research Institute	3/24/25
U01CA260588	SARS-CoV-2-reactive tissue-resident memory T cells in healthy and cancer subjects	La Jolla Institute For Immunology	3/24/25
U01CA261277	Casual, Statistical and Mathematical Modeling with Serologic Data	Harvard School Of Public Health	3/24/25
U01DA040381-05S2	Community-Engaged Research on COVID-19 Testing Among Underserved and/or Vulnerable Populations	Florida International University	3/24/25
U01DA053903	Wastewater Assessment for Coronavirus in Kentucky: Implementing Enhanced Surveillance Technology	University Of Kentucky	3/24/25
U01DA057849	Supported employment to create a community culture of SARS-CoV-2 rapid testing among people who inject drugs: PeerConnect2Test	University Of Oregon	3/24/25
U01MD017412	Sin Duda: a community-driven approach to expand reach, access and uptake of COVID-19 home-based tests for at risk Latinos	Johns Hopkins University	3/24/25
U01MD017426	Puerto Rico Community Action Research and Engagement (PR-CARE) to Eliminate Disparities in Diagnostic of COVID-19 among Rural Underserved and Vulnerable Populations.	University Of Puerto Rico Med Sciences	3/24/25
U01MD017434	COVID-19 and Southeast Asian Americans	California State University Northridge	3/24/25
U19AI171403	Antiviral Countermeasures Development Center (AC/DC)	Emory University	3/24/25
U19AI171413	UTMB-Novartis Alliance for Pandemic Preparedness	University Of Texas Med Br Galveston	3/24/25
U19AI171954	Midwest AViDD Center	University Of Minnesota	3/24/25
U24LM013755	RADx-Rad Discoveries & Data: Consortium Coordination Center Program Organization	Yale University	3/24/25
U24MD016258	RADx-UP CDCC	Duke University	3/24/25
U24TR001608	ACTIV-6	Duke University	3/24/25
U24TR001608	ACTIV-6	Duke University	3/24/25
U54CA260492	Johns Hopkins Excellence in Pathogenesis and Immunity Center for SARS-CoV-2 (JH-EPICS)	Johns Hopkins University	3/24/25
U54CA260517	Mechanisms and Duration of Immunity to SARS-CoV-2	Stanford University	3/24/25
U54CA260543	North Carolina Seronet Center for Excellence	Univ Of North Carolina Chapel Hill	3/24/25
U54CA260560	Vulnerability of SARS- CoV-2 Infection in Lung Cancer Based on Serological Antibody Analyses	Icahn School Of Medicine At Mount Sinai	3/24/25
U54CA260563	Immune Regulation of COVID-19 Infection in Cancer and Autoimmunity	Emory University	3/24/25
U54CA260563-02S3	Administrative Supplement for Emory SeroNet "Immune Regulation of COVID-19 Infection in Cancer and Autoimmunity"	Emory University	3/24/25
U54CA260581	Tulane University COVID Antibody and Immunity Network (TUCAIN)	Tulane University Of Louisiana	3/24/25

U54CA260581-02S3	Tulane University COVID Antibody and Immunity Network (TUCAIN) Supplement	Tulane University Of Louisiana	3/24/25
U54CA260582	Center for Serological Testing to Improve Outcomes from Pandemic COVID-19 (STOP-COVID)	Ohio State University	3/24/25
U54CA260582-02S3	Center for Serological Testing to Improve Outcomes from Pandemic COVID-19 (STOP-COVID)	Ohio State University	3/24/25
U54CA260591	Diversity and Determinants of the Immune-Inflammatory Response to SARS-CoV-2	Cedars-Sinai Medical Center	3/24/25
U54EB015408-08S1	Point of Care Technology Research Center in Primary Care	Massachusetts General Hospital	3/24/25
UM1AI068618-18S2	CoVPN 3008 Multi-Center, Randomized, Efficacy Study of Early vs Deferred Vaccination with COVID-19 mRNA Vaccine in Regions with SARS-CoV-2 Variants of Concern - LC GY18	Fred Hutchinson Cancer Center	3/24/25
UM1AI068635-18S1	CoVPN 3008 2022-2023	Fred Hutchinson Cancer Center	3/24/25
UM1AI148684-03S1	Leadership Group for the Infectious Diseases Clinical Research Consortium (IDCRCLG)	Emory University	3/24/25
U19AG078558	Alzheimer's Disease and Alzheimer's Disease Related Dementias in Prediabetes and Type 2 Diabetes: The Diabetes Prevention Program Outcomes Study AD/ADRD Project	Columbia University Health Sciences	3/25/25
R13ES036080	Society of Toxicology Undergraduate Diversity Program	Society Of Toxicology	3/26/25
U01ES036366	Examining Anti-Racist Healing in Nature to Protect Telomeres of Transitional Age BIPOC for Health Equity.	San Francisco State University	3/26/25
U01ES036366-03S1	Examining Anti-Racist Healing in Nature to Protect Telomeres of Transitional Age BIPOC for Health Equity.	San Francisco State University	3/26/25
U01ES036366-03S2	Examining Anti-Racist Healing in Nature to Protect Telomeres of Transitional Age BIPOC for Health Equity.	San Francisco State University	3/26/25
R01ES035053	An assessment of environmental and neighborhood-level risk factors for subfertility among Black women in the U.S.	Boston University Medical Campus	3/27/25
R01ES035053-03S1	An assessment of environmental and neighborhood-level risk factors for subfertility among Black women in the U.S.	Boston University Medical Campus	3/27/25
T34GM136483	U-RISE at Texas State University	Texas State University	3/27/25
T34GM140948	U-RISE at Kennesaw State	Kennesaw State University	3/27/25
T34GM145508	U-RISE at Clark Atlanta University	Clark Atlanta University	3/27/25
T34GM145529	U-RISE at the University of Texas at El Paso	University Of Texas El Paso	3/27/25
T34GM145533	U-RISE at Marquette University	Marquette University	3/27/25
T34GM149434	U-RISE at the UNC Pembroke	University Of North Carolina At Pembroke	3/27/25
T34GM149449	U-RISE at University of Alaska Anchorage ("Biomed U-RISE")	University Of Alaska Anchorage	3/27/25
T34GM149459	U-RISE at City College of New York	City College Of New York	3/27/25
T34GM149461	U-RISE Program at San Jose State University	San Jose State University	3/27/25
T34GM149475	U-RISE at Queens College, CUNY	Queens College	3/27/25
T34GM149490	U-RISE at Brooklyn College	Brooklyn College	3/27/25
T34GM153538	U-RISE at the University of West Florida	University Of West Florida	3/27/25
T34GM153609	U-RISE at Rutgers University - Camden	Rutgers The State Univ Of Nj Camden	3/27/25
R01MD016738-04S1	The ADELANTE Trial: Testing a multi-level approach for improving household food insecurity and glycemic control among Latinos with diabetes	Stanford University	3/28/25
R01MD018255-03S1	Recovery Finance: Financial health and mental health after incarceration	Yale University	3/28/25
T34GM145509	U-RISE at Nova Southeastern University	Nova Southeastern University	3/31/25
T34GM149492	U-RISE at Cal Poly	California Poly State U San Luis Obispo	3/31/25
K01AG065440	Creating Innovative Vaccine Messaging by Engaging in Patient-Centered Design with Non-Vaccinating Older Adults	University Of Iowa	4/1/25
K22CA258675	Addressing HPV vaccination disparities through tailored messaging for hesitant families	Rutgers Biomedical And Health Sciences	4/1/25
K22CA288932	Cancer Misinformation and Use of Complementary and Alternative Therapy (CAM) among Patients with Cancer.	Hackensack University Medical Center	4/1/25
R00CA248720	Cancer misinformation on social media and its correction	Northeastern University	4/1/25
R01AR080089	Leveraging Community-Academic Partnerships and Social Networks to Disseminate Vaccine-Related Information and Increase Vaccine Uptake Among Black Individuals with Rheumatic Diseases	Northwestern University At Chicago	4/1/25
R01CA248216	Promoting HPV Vaccination among Young Adults in Texas	University Of Tx Md Anderson Can Ctr	4/1/25
R01CA248216-04S1	Promoting HPV Vaccination among Young Adults in Texas	University Of Tx Md Anderson Can Ctr	4/1/25
R01CA273208	Conversational Agents to Improve HPV Vaccine Acceptance in Primary Care	Tufts Medical Center	4/1/25
R01DA054990	Community Developed Technology-Based Messaging to Increase SARS-CoV-2 Vaccine Uptake Among People Who Inject Drugs	Ndri-Usa, Inc.	4/1/25

R01MD016834	A multidimensional Digital Approach to Address Vaccine Hesitancy and Increase COVID-19 Vaccine Uptake among African American Young Adults in the South	Florida State University	4/1/25
R01MD016864	K-VAC: Kentucky Vaccinating Appalachian Communities	University Of Kentucky	4/1/25
R01MD016880	Increasing COVID-19 Vaccine Uptake among Latinos through a Targeted Clinical and Community-behavioral Intervention	San Diego State University	4/1/25
R01MD016882	Community-based Design and Evaluation of a Conversational Agent to Promote SARS-COV2 Vaccination in Black Churches	Northeastern University	4/1/25
R01MD016992	Addressing COVID 19 Vaccine Hesitancy in Rural Community Pharmacies Reducing Disparities Through an Implementation Science Approach	Univ Of North Carolina Chapel Hill	4/1/25
R01MD017364	REDES: a peer network and mobile health (mHealth) enhanced CHW model to maximize COVID-19 vaccination among low income Latinos	Johns Hopkins University	4/1/25
R01MD018343	LatiNET, a Multilevel Social Network Model to Examine and Address SARS-CoV-2 Misinformation in Low-Income Latinx Communities.	University Of Miami School Of Medicine	4/1/25
R01MD019024	Advancing communication strategies to support future HIV vaccine use among African Americans in the South.	Wake Forest University Health Sciences	4/1/25
R01MD019235	Improving COVID-19 Vaccine Uptake Among Racial and Ethnic Minority Groupswith Rheumatic Diseases	University Of Alabama At Birmingham	4/1/25
R01MD019686	Community - based behavioral intervention to increase COVID - 19 and influenza vaccination for African American/ Black and Latino persons: An optimization randomized controlled trial	New York University	4/1/25
R01MD019765	Influence of Social Media, Social Networks, and Misinformation on Vaccine Acceptance Among Black and Latinx Individuals	University Of California-Irvine	4/1/25
R01MH132500	Evaluating a Multilevel Communication Campaign to Increase HIV Vaccine Trial Enrollment	Fred Hutchinson Cancer Center	4/1/25
R21MD019388	Integrated Network Analysis of RADx-UP Data to Increase COVID-19 Testing and Vaccination Among Persons Involved with Criminal Legal Systems (PCLS)	Brown University	4/1/25
R21MD019764	COVID-19 Vaccine Coverage and General Vaccine Hesitancy in Rural Areas in the United States	Ohio State University	4/1/25
R25GM150142	Eradicating Misconceptions about Viruses using Multimodal Trace Data in an Intelligent Game-based Environment across Educational Contexts	University Of Idaho	4/1/25
R25GM150172	PBS NewsHour STEM StoryMaker: Project-based learning for youth health literacy and biomedical career awareness through journalism and storytelling	Weta Tv 26	4/1/25
R34CA283483	Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa	Brigham And Women's Hospital	4/1/25
R37CA253279	HPV ECHO: Increasing the adoption of evidence-based communication strategies for HPV vaccination in rural primary care practices	Pennsylvania State Univ Hershey Med Ctr	4/1/25
R37CA259210	An inoculation theory-based messaging intervention addressing misinformation about HPV vaccine on social media: The Inoculate for HPV Vaccine randomized controlled trial	University Of Pennsylvania	4/1/25
F31GM151846	Exploring the functional role of tubulin methylation and its regulation by mes-4/NSD in C. elegans	Baylor College Of Medicine	4/2/25
F31GM155995	The Role of the Adaptor Protein Enkurin in Left-Right Patterning- a Promising Link Between Polycystin-2 and Calcium Signaling	Princeton University	4/2/25
K12GM088021	Academic Science Education and Research Training	University Of New Mexico Health Scis Ctr	4/2/25
K12GM119955	The Minnesota IRACDA Program	University Of Minnesota	4/2/25
R01GM138700	Scaling Up Culturally Affirming Pathways to Biomedical Faculty Careers for Native Scholars	University Of California, San Francisco	4/2/25
R25GM069234	YEARS 19 - 23: BCM POST-BACCALAUREATE RESEARCH EDUCATION PROGRAM	Baylor College Of Medicine	4/2/25
T32GM135742	UCSC IMSD	University Of California Santa Cruz	4/2/25
T32GM140951	Graduate Research Training Initiative for Student Enhancement (G-RISE) (T32) at Rutgers University-Newark	Rutgers The State Univ Of Nj Newark	4/2/25
T32GM152777	Baylor College of Medicine Initiative for Maximizing Student Development	Baylor College Of Medicine	4/2/25
T32GM154636	Texas Doctoral Bridge Program	Texas State University	4/2/25
T34GM145539	MARC at the University of Nevada, Reno	University Of Nevada Reno	4/2/25
T34GM149430	MARC at San Diego State University	San Diego State University	4/2/25
T34GM149455	U-RISE at St. Mary's University	St. Mary's University	4/2/25
T34GM149474	U-RISE at University of Detroit Mercy	University Of Detroit Mercy	4/2/25
K99DA060983	The Impact of Social-Contextual Stressors on Psychopharmacological Mechanisms of Smoking Cessation and Relapse among Socioeconomically Disadvantaged Young Adults who Smoke Cigarettes	Brown University	4/7/25
OT2OD035592	Proyecto Juntos	Southeast Arizona Area Health Education Center	4/7/25
OT2OD035592-01S1	Proyecto Juntos	Southeast Arizona Area Health Education Center	4/7/25
OT2OD035605-01S1	Partnership to Optimize Equity in Maternal and Infant Health	Delta Health Alliance, Inc.	4/7/25

OT2OD035606	Achieving Equity in Farmworker Health Through Community-Led Research	Campesinos Sin Fronteras	4/7/25
OT2OD035606-01S1	Achieving Equity in Farmworker Health Through Community-Led Research	Campesinos Sin Fronteras	4/7/25
OT2OD035609	Healthy and Livable Bronx Partnership	Bronxworks, Inc.	4/7/25
OT2OD035609-01S1	Healthy and Livable Bronx Partnership	Bronxworks, Inc.	4/7/25
OT2OD035636	Agricultural Workers Digital Equity Initiative	Nc State Dept/Hlth & Human Services	4/7/25
OT2OD035636-01S1	Agricultural Workers Digital Equity Initiative	Nc State Dept/Hlth & Human Services	4/7/25
OT2OD035677	Puerto Rico Collaborative Advancement of Research, Innovations, Best Practices and Equity for Children, Youth and Families (PR-CARIBE)	Grupo Nexos Inc.	4/7/25
OT2OD035677-01S1	Puerto Rico Collaborative Advancement of Research, Innovations, Best Practices and Equity for Children, Youth and Families (PR-CARIBE)	Grupo Nexos Inc.	4/7/25
OT2OD035746	Creating Statewide Community Partnerships: Spanning Boundaries between Public Health, Emergency Housing & Criminal Justice	Face Addiction Now	4/7/25
OT2OD035746-01S1	Creating Statewide Community Partnerships: Spanning Boundaries between Public Health, Emergency Housing & Criminal Justice	Face Addiction Now	4/7/25
OT2OD035764	Cancer in Your Community: Strategies to Reduce Cancer and Chronic Disease in the Arkansas Delta	Arkansas Cancer Coalition	4/7/25
OT2OD035764-01S1	Cancer in Your Community: Strategies to Reduce Cancer and Chronic Disease in the Arkansas Delta	Arkansas Cancer Coalition	4/7/25
OT2OD035801	Strengthening Community-Driven Safety-Net Interventions to Improve Health and Economic Equity	Access Health Inc	4/7/25
OT2OD035801-01S1	Strengthening Community-Driven Safety-Net Interventions to Improve Health and Economic Equity	Access Health Inc	4/7/25
OT2OD035839	Reducing Health Disparities through Enhanced Mobility Support and Access	Feonix - Mobility Rising	4/7/25
OT2OD035839-01S1	Reducing Health Disparities through Enhanced Mobility Support and Access	Feonix - Mobility Rising	4/7/25
OT2OD035845	Humanitarian Health Care Network: Bringing the Most Vulnerable to Care	Migrant Clinicians Network, Inc.	4/7/25
OT2OD035845-01S1	Humanitarian Health Care Network: Bringing the Most Vulnerable to Care	Migrant Clinicians Network, Inc.	4/7/25
OT2OD035883	Addressing Food Insecurity in Underserved Communities	Health Choice Network, Inc.	4/7/25
OT2OD035883-01S1	Addressing Food Insecurity in Underserved Communities	Health Choice Network, Inc.	4/7/25
OT2OD035940	Watts Rising: A Vision for a Healthier Watts	Housing Authority Of The City Of Los Angeles	4/7/25
OT2OD035940-01S1	Watts Rising: A Vision for a Healthier Watts	Housing Authority Of The City Of Los Angeles	4/7/25
U24NR021014	Advancing Health Equity Through Innovative Community Capacity Building, Data Science & Delivering Community-Centered Structural Interventions & Outcomes: Drexel's ComPASS Coordinating Center (C3)	Drexel University	4/7/25
UC2CA293569	Partners in Research: Building capacity for community-driven research to advance health equity	University Of Michigan At Ann Arbor	4/7/25
UC2CA293782	ComPASS Health Equity Research Hub at UMB	University Of Maryland Baltimore	4/7/25
UC2CA293786	ComPASS Health Equity Research Hub at Yale	Yale University	4/7/25
UC2CA293834	The SHHare Community Project: The Shared Hub for Health Action Research and Equity in Community-led Interventions	New York University School Of Medicine	4/7/25
UC2CA293850	Southeast Center for Health Achievement and Growth in Equity (SEACHANGE) Hub	University Of Mississippi Med Ctr	4/7/25
U54CA267730	Fostering Institutional Resources for Science Transformation: The FLORIDA-FIRST Health-Science Brigade	Florida State University	4/8/25
U54CA267738	Cornell FIRST	Cornell University	4/8/25
U54CA267746	UAB/Tuskegee Faculty Institutional Recruitment for Sustainable Transformation (UAB/TU FIRST) Partnership (NIH U54)	University Of Alabama At Birmingham	4/8/25
U54CA267776	NIH FIRST Cohort Cluster Hiring Initiative at Icahn School of Medicine at Mount Sinai	Icahn School Of Medicine At Mount Sinai	4/8/25
U54CA267789	SDSU FUERTE: Faculty United towards Excellence in Research and Transformational Engagement	San Diego State University	4/8/25
U54CA272163	NURTURE: Northwestern University Recruitment to Transform Under-Representation and achieve Equity	Northwestern University At Chicago	4/8/25
U54CA272167	UNM FIRST: Promoting Inclusive Excellence in Neuroscience and Data Science	University Of New Mexico	4/8/25
U54CA272205	University of Maryland FIRST Program	University Of Maryland Baltimore	4/8/25
U54CA272220	UC San Diego FIRST Program	University Of California, San Diego	4/8/25
U54CA280805	Michigan Program for Advancing Cultural Transformation (M-PACT) in Biomedical and Health Sciences	University Of Michigan At Ann Arbor	4/8/25
U54CA280868	The Medical District UTSW-D FIRST Program	Ut Southwestern Medical Center	4/8/25
U54CA280922	UTEP FIRST: United Toward Equity and Progress: Faculty Institutional Recruitment for Sustainable Transformation	University Of Texas El Paso	4/8/25
R01HG012824	Genetic and social determinants of pharmacological health outcomes in ancestrally diverse populations	University Of California, San Francisco	4/11/25

R01HG012824-02S1	Genetic and social determinants of pharmacological health outcomes in ancestrally diverse populations (Recto)	University Of California, San Francisco	4/11/25
R01HG012824-02S2	Genetic and social determinants of pharmacological health outcomes in ancestrally diverse populations (Warren)	University Of California, San Francisco	4/11/25
R01AI110700	Cell entry, cross-species transmission and pathogenesis of novel coronavirus from	Univ Of North Carolina Chapel Hill	4/14/25
R01AI157155	Human antibody-based countermeasures against the Wuhan Coronavirus SARS-CoV-2	Washington University	4/14/25
R21HG013814	APOL1 as a model to quantify and identify environmental modifiers of genetic associations in diverse populations	Case Western Reserve University	4/15/25
T32GM140953	G-RISE at Oklahoma State University	Oklahoma State University Stillwater	4/30/25

EXHIBIT B

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

Office of The Director, National Institutes of Health (OD (https://www.nih.gov/institutes-nih/nih-office-director))

National Eye Institute (NEI (https://www.nei.nih.gov/))

National Heart, Lung, and Blood Institute (NHLBI (https://www.nhlbi.nih.gov/))

National Human Genome Research Institute (NHGRI (https://www.genome.gov/))

National Institute on Aging (NIA (https://www.nia.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))

National Institute of Allergy and Infectious Diseases (NIAID (https://www.niaid.nih.gov/))

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS (https://www.niams.nih.gov/))

National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://www.nibib.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (https://www.nichd.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))

National Institute on Drug Abuse (NIDA (https://www.drugabuse.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

National Institute of General Medical Sciences (NIGMS (https://www.nigms.nih.gov/))

National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml))

National Institute of Nursing Research (NINR (https://www.ninr.nih.gov/))

National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))

Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP (https://orip.nih.gov/))

National Cancer Institute (NCI (https://www.cancer.gov/))

National Institute on Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/)), November 22, 2024 - Participation added (NOT-DK-25-007 (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-25-007.html))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of Research on Women's Health (ORWH (https://orwh.od.nih.gov/))

Office of Data Science Strategy (ODSS (https://datascience.nih.gov/about/odss))

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their

respective areas of research interest and requirements at the ***Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/guide/contacts/PA-25-168.html)*** website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

Funding Opportunity Title

Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32)

Activity Code

T32 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t32&Search.x=0&Search.y=0&Search_Type=Activity) Institutional National Research Service Award (NRSA)

Announcement Type

Reissue of PA-23-048 (https://grants.nih.gov/grants/guide/pa-files/PA-23-048.html)

Related Notices

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=41857) associated with this funding opportunity

- **December 10, 2024** - Notice of Correction to Eligibility Information and Application Instructions for the Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32) (PA-25-168). See Notice NOT-OD-25-036 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-25-036.html).
- **November 22, 2024** - Notice of NIDDK Participation in PA-25-168: "Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32)". See Notice NOT-DK-25-007 (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-25-007.html).
- **November 18, 2024** - Notice of Informational Webinar for NIGMS-Supported Postdoctoral Clinician-Scientists Institutional Training Programs (T32). See Notice NOT-GM-25-005 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-25-005.html).
- **April 4, 2024** - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html).

Funding Opportunity Number (FON)

PA-25-168

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.310, 93.313, 93.837, 93.233, 93.838, 93.839, 93.840, 93.286, 93.273, 93.213, 93.397, 93.396, 93.399, 93.398, 93.855, 93.351, 93.859, 93.361, 93.279, 93.113, 93.867, 93.172, 93.242, 93.866, 93.865, 93.846, 93.173, 93.847

Funding Opportunity Purpose

The National Institutes of Health (NIH) will award Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants (T32) to eligible, domestic institutions to develop and/or enhance predoctoral and postdoctoral research training, including short-term research training, to help ensure that a diverse and highly trained workforce is available to meet the needs of the Nation's biomedical, behavioral, and clinical research agenda. Research training programs are expected to incorporate engaging, didactic, research, and career development elements to prepare trainees for careers that will have a significant impact on the health-related research needs of the Nation. Programs proposing only short-term predoctoral research training should not apply to this announcement, but rather to the Kirschstein-NRSA Short-Term

Institutional Research Training Grant Program (T35) exclusively reserved for predoctoral, short-term research training.

This Notice of Funding Opportunity (NOFO) does not allow Trainees to lead an independent clinical trial, but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Funding Opportunity Goal(s)

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

Key Dates

Posted Date November 15, 2024

Open Date (Earliest Submission Date) December 25, 2024

Letter of Intent Due Date(s) Not Applicable

The following table includes NIH standard due dates (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
January 25, 2025 *	January 25, 2025 *	May 07, 2025 *	July 2025	October 2025	December 2025
May 25, 2025 *	May 25, 2025 *	September 07, 2025 *	November 2025	January 2026	April 2026
September 25, 2025 *	September 25, 2025 *	January 07, 2026 *	March 2026	May 2026	July 2026
January 25, 2026 *	January 25, 2026 *	May 07, 2026 *	July 2026	October 2026	December 2026
May 25, 2026 *	May 25, 2026 *	September 07, 2026 *	November 2026	January 2027	April 2027
September 25, 2026 *	September 25, 2026 *	January 07, 2027 *	March 2027	May 2027	July 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	October 2027	December 2027
May 25, 2027 *	May 25, 2027 *	September 07, 2027 *	November 2027	January 2028	April 2028
September 25, 2027 *	September 25, 2027 *	January 07, 2028 *	March 2028	May 2028	July 2028

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date	May 05, 2028
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the Training (T) Instructions in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed to do otherwise (in this NOFO or in a Notice from the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/url_redirect.php?id=11164)). Conformance to all requirements (both in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400), follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (/grants/guide/ApplyButtonSplash.cfm?dest=https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-168) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

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- Section VI. Award Administration Information
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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (https://researchtraining.nih.gov/programs/training-grants/T32-a) (NRSA) website.

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Institutional NRSA programs allow the Training Program Director/Principal Investigator (Training PD/PI) to select trainees and develop an enhanced program of coursework, mentored research experiences, and technical, operational and professional skills development that provides added value to already existing programs and prepares the appointed trainees for careers in the biomedical research workforce (the breadth of careers that sustain the biomedical research enterprise, including but limited to careers as independent NIH-funded investigators).

The grant offsets the costs of stipends, tuition and fees, and training related experiences, including health insurance, for the appointed trainees in accordance with the approved NIH support levels. The proposed institutional research training program may complement other ongoing research training and career development programs at the applicant organization but must be clearly distinct from related program currently receiving Federal support.

Purpose

The purpose of the Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (T32) program is to develop and/or enhance research training opportunities for individuals interested in careers in biomedical, behavioral or social sciences, and clinical research, in health services research, or in any other discipline relevant to the NIH mission. NIH encourages biomedical research training to keep pace with the rapid evolution of the biomedical research enterprise that is increasingly complex, interdisciplinary, quantitative, and collaborative. Programs should prepare trainees to effectively engage in a research enterprise characterized by increased breadth in the backgrounds of individuals participating, the approaches taken to investigate research questions, and the range of careers that biomedical doctoral recipients are pursuing. There is also increasing recognition of the need to enhance the reproducibility of biomedical research results through scientific rigor and transparency, and the skills of mentors to effectively engage a more diverse trainee population.

Each proposed program should provide rigorous research training, and mentored research experiences, and are expected to help trainees develop:

- The skills to independently acquire the knowledge needed to advance their chosen field;
- The ability to think critically and independently, and to identify important research questions and approaches that push forward the boundaries of their areas of study;
- An understanding of the health-related sciences and the relationship of their research training to health and disease;
- A strong foundation in scientific reasoning, rigorous and reproducible research design, experimental methods, quantitative and computational approaches, and data analysis and interpretation;
- The skills to conduct research in the safest manner possible, and a commitment to approaching biomedical research responsibly, ethically, and with integrity;
- Experience initiating, conducting, interpreting and presenting rigorous and reproducible research with increasing self-direction;
- The ability to work effectively in teams with colleagues from a variety of cultural and scientific backgrounds and to promote inclusive and supportive scientific research environments;
- The skills to teach and communicate scientific research methodologies and findings to a wide variety of audiences (e.g., discipline-specific, across disciplines, and the public); and
- The knowledge, professional skills, and experiences required to identify and transition into careers in the biomedical research workforce.

Program Considerations

This NOFO is intended to support rigorous research training programs that will promote the development of a biomedical research workforce that will benefit from the full range of perspectives, experiences and backgrounds needed to advance and translate discovery for the benefit of all. NIH expects organizations to engage in outreach and recruitment activities to encourage individuals from diverse backgrounds, including individuals from underrepresented groups (see the Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) to participate in the program. Consistent with existing NIH practices and applicable law: (1) Funded programs may not use the race, ethnicity, or sex (including gender identity, sexual orientation, or transgender status) of a trainee or faculty candidate as an eligibility or selection criterion, and (2) NIH does not use the race, ethnicity, or sex of trainee candidates, trainees, or faculty in the application review process or funding decisions. Applicants and award recipients are encouraged to consult with their General Counsel to ensure all applicable laws and regulations are being followed in program design and implementation.

Applicants are expected to identify unique training goals and objectives (i.e., specific and measurable outcomes the program intends to achieve) and develop plans to implement evidence-informed training and mentoring activities (i.e., approaches that are grounded in the literature and from evaluations of existing relevant training programs) to address those needs and objectives.

Inclusive, Safe, Accessible and Supportive Research Training Environments that Promote Scientific Rigor

Funded programs are expected to implement robust plans to develop inclusive, safe, accessible, and supportive research training environments to maximize success for all individuals in the training program. Specifically, funded programs should have institutional and departmental environments where individuals from all backgrounds, including those from underrepresented groups, are welcomed and feel integrated into and supported by the biomedical research community. Funded programs are also expected to implement plans to enhance trainee retention (i.e., to sustain the scientific interests and participation of trainees from all backgrounds), which may be integrated with plans for mentor training (see below). Safety in research training environments should encompass:

- Environments free from harassment, bullying and intimidation (https://grants.nih.gov/grants/policy/harassment.htm), in which everyone participating is treated in a respectful and supportive manner,
- Laboratory and clinical settings where individuals exercise the highest standards of practice for chemical, biological and physical safety (for more information see examples of Laboratory Safety Training Guidelines (https://nigms.nih.gov/training/Pages/Laboratory-Safety-Training-and-Guidelines.aspx)), and
- Practices at the institutional leadership and research community levels that demonstrate core values and behaviors to emphasize safety over competing goals.

Biomedical research and the resulting scientific knowledge are increasingly complex, multidisciplinary, and collaborative in nature. Training PDs/PIs are encouraged to develop institutional training programs that will provide trainees with education and experience in a variety of rigorous and reproducible scientific approaches, systems for study, tools, and technologies. Consideration of team-based research approaches may also be warranted depending upon the goals of the proposed training program. Funded training programs must ensure that trainees have a solid foundation in methods to enhance data reproducibility through rigor and transparency (for examples, see NIH Rigor and Reproducibility Training (https://www.nih.gov/research-training/rigor-reproducibility/training)).

Mentor Training

Effective mentorship is critical to the development and retention of scientists and the advancement of research. Studies have shown that effective mentorship has overall positive effects on mentees, mentors and the overall research environment (e.g., improved academic achievement, retention, and degree attainment, career satisfaction, career commitment of trainees from all backgrounds, and enhanced integration of trainees from underrepresented groups into the biomedical academic community; see National Academies of Sciences, Engineering, and Medicine 2019, The Science of Effective Mentorship in STEMM (https://www.nationalacademies.org/our-work/the-science-of-effective-mentoring-in-stemm)). Formal training, and ongoing professional development in effective mentoring practices has been shown to improve the knowledge and skills of research mentors across career stages.

Funded training programs are expected to support effective mentorship by ensuring all program faculty complete formal mentor training and periodic refreshers. Programs should consider the following as potential mentor training components, and are encouraged to adapt to program and trainee needs:

- Aligning expectations.
- Maintaining effective communication.
- Fostering independence.
- Assessing understanding.
- Enhancing professional development.
- Addressing equity and inclusion.
- Articulating a mentoring philosophy and plan.

Trainee Career Development

Scientists supported by NRSA training programs pursue a wide variety of careers in the biomedical research workforce in a variety of sectors. These include research-intensive careers in academia, industry and government, and research-related careers in academic institutions, government agencies, for-profit businesses, and private foundations that directly benefit the broader biomedical research enterprise. Training PDs/PIs should make available appropriate skills training so that trainees are prepared to apply for subsequent independent support for their training, career development or research program (e.g., an individual fellowship award, mentored career development award, or research project grant), as appropriate for their career stage and interest. Training programs should also make available structured career development opportunities (e.g., workshops, individual development plans, informational interviews, shadowing, internships) so that trainees will obtain a working knowledge of various potential career paths that would make strong use of the knowledge and skills gained during research training, and the steps, experiences, networks, and credentials required to transition successfully to the next stage of their chosen career.

Considerations for Clinicians and Dual-degree Students

Past studies have shown that health professional trainees who train in programs with postdoctoral researchers who have intensive research backgrounds are more likely to work with their institutions to apply for and receive subsequent research grant support. Programs that emphasize research training for individuals with the MD or other health-professional degrees are therefore encouraged to develop interactions with basic science departments and include trainees with research doctorates when this approach is consistent with the goals of the proposed training program.

Institutional research training grants must be used to support a program of full-time research training. Within the full-time training period, research trainees who are also training as clinicians must devote their time to the proposed research training and confine clinical duties to those that are an integral part of the research training experience or can be conducted in the allowable additional 25% of their time (e.g., 10 hours per week) that may be devoted to clinical employment. The program may not be used to support studies leading to the MD, DDS, or other clinical, health-professional degrees except when those studies are part of a formal combined research degree program, such as the MD/PhD. Similarly, trainees may not accept NRSA support for clinical training that is part of residency training leading to clinical certification in a medical or dental specialty or subspecialty. It is permissible and encouraged, however, for clinicians to engage in NRSA-supported, full-time postdoctoral research training even when that experience is creditable toward certification by a clinical specialty or subspecialty board.

Other Considerations

Institutional commitment and support for the proposed training program are important elements of the application. The research training program may complement and synergize with other ongoing federally supported research training and career development programs at the applicant institution (e.g., in the development of skills needed for careers in the biomedical research workforce that are not discipline-specific); however, the research training goals and objectives must be distinct from related programs at the same institution currently receiving federal support. Funded programs are expected to provide evidence of accomplishing the training goals in progress reports and upon renewal, to make aggregate data on training and career outcomes publicly available, and are strongly encouraged to disseminate successful training practices to the broader training community. Training grant funds may not be used solely as a vehicle to provide stipends for trainees to conduct research.

The duration of training, the transition of trainees to individual support mechanisms, and their transition to the next career stage are important considerations in institutional training programs. Also, an important consideration is the engagement of trainees in their training goals, process and activities through the program that enhances what they may be getting in existing programs within the institution. Training PD/PIs should limit appointments to individuals who plan to remain in the training program for no less than two years, whether that support comes from a training grant or some combination of NRSA and non-NRSA programs institution.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training. Short-term positions should be requested at the time of application, as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11.1_general.htm). Research training programs solely for short-term research training should not apply to this announcement, but rather the T35 NRSA NOFO, which can be found in the NIH Training Kiosk. (https://researchtraining.nih.gov/programs/training-grants)

This Notice of Funding Opportunity (NOFO) does not support of Trainees to lead an independent clinical trial, but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this NOFO, prospective applicants **MUST** consult the **Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/guide/contacts/PA-25-168.html)**, to make sure that their application is appropriate for the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument	Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	New Renewal Resubmission Revision The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) provide details on these application types. Only those application types listed here are allowed for this NOFO.
Clinical Trial?	Not Allowed: Only accepting applications that do not propose clinical trials. Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a

mentor or co-mentor.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited, but need to reflect the actual needs of the proposed project.

Recipients are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (*NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards for T32 institutional NRSA research training grants may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Ruth L. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

Travel for trainees to attend scientific meetings and workshops that the institution determines to be necessary for the individual's research training experience is an allowable expense for predoctoral and postdoctoral trainees. This includes trainees on short-term appointments. Trainees must be appointed to the training grant at the time of the actual travel for this to be an allowable cost.

The amount of funds provided for trainee travel may vary by NIH Institute or Center; applicants are encouraged to consult the Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/guide/contacts/PA-25-168.html) for further information.

Training Related Expenses

NIH will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, mentor training activities, equipment, research supplies, and faculty/staff travel directly related to the research training program. The most recent levels of training related expenses are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Indirect Costs	Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of $25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Local Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants

should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information.

- System for Award Management (SAM) (https://grants.nih.gov/grants/guide/url_redirect.php?id=82390) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.

- NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.

- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with their organization to develop an application for support. Individuals from diverse backgrounds, including individuals from underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html).

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy (//grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

The PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be responsible for the selection and appointment of trainees to the approved research training program, and for the overall direction, management, administration, and evaluation of the program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required. The PD/PI has responsibility for the day-to-day administration of the program and is responsible for appointing members of the Advisory Committee (when applicable), using their recommendations to determine the appropriate allotment of funds. Additional PDs/PIs, including individuals with experience in areas relevant to the program goals may be included to achieve the training goals.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement Section 1.2 Definition of Terms (//grants.nih.gov/grants/guide/url_redirect.php?id=11126).

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is programmatically distinct.

NIH will not accept duplicate or highly overlapping applications under review at the same time per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//grants.nih.gov/grants/guide/url_redirect.php?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423))

Preceptors/Mentors

Program faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support in the area of the proposed research training program. Programs are encouraged to recruit prospective preceptors/mentors from a wide variety of backgrounds, for example, faculty from underrepresented groups (see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) and faculty at different career stages (for example, early stage investigators as well as senior faculty). When building a training team, programs should include faculty who are committed to training, mentoring, and providing inclusive, safe, accessible, and supportive research training environments. All program faculty should have a mentoring philosophy appropriately tailored to the needs of potential trainees that ensures trainees will receive the tailored mentorship needed to develop skills and advance their career. Program faculty should also have sufficient time to commit to training given their other professional obligations.

Trainees

The applicant organization will select the trainees to be supported by the research training program and is responsible for establishing trainee eligibility and selection criteria that are consistent with applicable law.

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the awarding unit, or when trainees are appointed to approved, short-term training positions.

Predoctoral trainees. Predoctoral trainees must be enrolled in a program leading to a PhD or in an equivalent research doctoral degree program. Health-professional students who wish to interrupt their studies for a year or more to engage in full-time research training before completing their formal training programs, are also eligible.

Postdoctoral trainees. Postdoctoral trainees must have received, as of the beginning date of the NRSA appointment, a Ph.D., M.D., D.D.S., or comparable doctoral degree from an accredited domestic or foreign institution. Comparable doctoral degrees include, but are not limited to, the following: D.M.D., DC, DO, DVM., OD, DPM, ScD, EngD, DrPH, DNSc, DPT, PharmD, ND (Doctor of Naturopathy), DSW, PsyD, as well as a doctoral degree in nursing research. Documentation by an authorized official of the degree-granting institution certifying all degree requirements have been met prior to the beginning date of the training appointment is acceptable. Individuals in postgraduate clinical training, who wish to interrupt their studies for a year or more to engage in full-time research training before completing their formal training programs, are also eligible.

Short-term trainees.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Training (T) Instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.php?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424 (R&R) Other Project Information

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Project Summary/Abstract. Provide an abstract of the entire application. Include the goals, objectives, rationale and design of the research training/career development program, as well as key activities in the training plan. Indicate the planned duration of appointments, the projected number of trainees/scholars including their levels (i.e., predoctoral, postdoctoral, short-term), and intended trainee/scholar outcomes.

Other Attachments. An Advisory Committee is not a required, but a highly recommended component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training program. The composition, roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee members should be named in the application if they have been invited to participate at the time the application is submitted. Renewal applications with Advisory Committees should include the names of all committee members during the past project period. Please name your file "Advisory_Committee.pdf".

The filename provided for each "Other Attachment" will be the name used for the bookmark in the electronic application in eRA Commons.

SF424(R&R) Senior/Key Person Profile Expanded

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

PHS 398 Cover Page Supplement

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Training Budget

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) with the following additional modifications:

- Include all personnel other than the Training PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.

PHS 398 Research Training Program Plan

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program
- Faculty, Trainees, and Training Record
- Other Training Program
- Appendix - Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the NOFO specifically instructs applicants to do so.

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

The following modifications apply:

Particular attention must be given to the required **Training Data Tables** (//grants.nih.gov/grants/guide/url_redirect.php?id=61169). Applicants should summarize, in the body of the application, key data from the tables that highlight the characteristics of the prospective candidate pool, faculty mentors, the educational and career outcomes of past participants, and other factors that contribute to the overall environment of the program.

Training Program

In addition to the information specified in the Application Guide, describe the following for each section of the Program Plan attachment:

Background

The application should clearly describe the goals (i.e., broad statement of purpose of the program), and objectives (i.e., specific measurable outcomes the program intends to achieve) of the proposed research training program. The program-specific goals and objectives should align with the Program Objective of this funding announcement while focusing on developing the specific skills required to be a well-trained scientist in the proposed scientific discipline(s).

The application should describe how the program will develop a diverse pool of well-trained scientists who have the technical, operational, and professional skills required to conduct research in a safe, ethically responsible and rigorous manner, and to enter careers in the biomedical research workforce as delineated in the Program Objective. The application should describe how the program will enhance the training environment and not simply provide financial support to trainees.

Program Plan

Program Administration (Training Program Director(s)/Principal Investigator(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PDs/PIs) will promote the success of the trainees and training program. Multiple PDs/PIs are encouraged, particularly when each brings a unique perspective and skill set that will enhance training. The application should expand on the information in the biosketch(es) to address how the PD/PI or PD/PI team has:

- The appropriate expertise (for example, a record of rigorous research), as well as the administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program.
- The time to commit sufficient effort to ensure the program's success, given other professional obligations (applicants should indicate the program director's percent effort in the proposed program).
- A demonstrated commitment to training future biomedical research researchers.
- Received training (or have a plan in place to ensure they receive training) on how to effectively mentor trainees from all backgrounds including trainees from groups underrepresented in the biomedical sciences (e.g., see Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) prior to the start of the program.

This section should describe how previous mentoring experiences of the PD(s)/PI(s) will support the success of the proposed training program.

Program Faculty

The application should describe (a) the faculty participants and (b) planned mentor training and oversight.

Faculty Participants, please describe:

- The efforts made to recruit a pool of prospective program faculty from a wide variety of backgrounds, for example, faculty from underrepresented groups, and a range of career stages and scientific disciplines relevant to the training goals, to provide potential role models within the training program and to enhance the training environment.

Mentor Training and Oversight, please describe:

- The planned strategy and administrative structure to oversee and monitor the program and ensure appropriate and timely trainee progress. This should include a mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty who continue to display unacceptable mentorship qualities from the training program.
- How the participating faculty are trained to ensure the use of evidence-informed mentoring practices that promote the development of trainees from all backgrounds, including trainees from groups underrepresented in the biomedical sciences. Include the planned format, duration, and frequency of mentor training activities for program faculty and a description of how mentor training has been tailored to the goals and objectives of the broader training program. Describe the major topics covered in mentor training. Examples of relevant topics include, but are not limited to:
    - Aligning expectations.
    - Maintaining effective communication.
    - Fostering independence.
    - Assessing scholars' understanding of scientific research.
    - Enhancing professional development.
    - Addressing equity and inclusion.
    - Articulating your mentoring philosophy and plan.

Proposed Training

In addition to the information specified in the Application Guide, describe:

- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, inclusion, and professional development, and how these activities will address the program's training goals and objectives.
- How trainees will be instructed on data science principles that are relevant to their areas of research. Examples include statistics, computational science, bioinformatics, data sharing and access, data management, data security, and data privacy in human subjects research.

Career Development

The proposed training should include a section on career development activities for trainees involved in the program, and should describe:

- How the pool of potential applicants and trainees will be provided with information about the overall biomedical research workforce employment landscape, the variety of careers in the biomedical research workforce for which their training would be useful, and the career outcomes of graduates of the program (e.g., on publicly accessible websites).
- How the proposed program will engage a range of potential employers to ensure the trainees will acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them and consistent with their values.

- How the training program or institution will provide appropriate experiential learning opportunities (e.g., internships, shadowing, informational interviews, teaching opportunities) that allow trainees to develop the professional skills and networks necessary to transition into careers in the biomedical research workforce.

Training Program Evaluation

The application should describe:

- How the proposed evaluation will assess the extent to which the overall program is effective in meeting its training goals and objectives, and whether the research training environment is inclusive and supportive of trainee development .
- The program's procedures for responding to program evaluation findings.

Trainee Candidates and Retention Plans

Through the narrative and summaries of the information presented in the Training Data Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and the attachments, the application should:

- Provide a strong justification for the number of requested trainee positions.
- Describe a multifactorial candidate review process (i.e., a process that considers metrics beyond previous institution, GPA, and standardized test scores) that will allow a broad group of research-oriented trainees who have taken advantage of the research opportunities available to them and are committed to contributing to the biomedical research enterprise the ability to participate in the training program. Programs are encouraged to consider individuals who have the potential to strongly benefit from, and with proper training and support, succeed in the program (see also, Program Considerations in section I above).

Retention Plans

Describe efforts to sustain the scientific interests as well as monitor the academic and research progress of trainees from all backgrounds within the program (i.e., retention), including those from underrepresented groups. Applicants are encouraged to consult the NIH's website to identify promising retention practices (https://extramural-diversity.nih.gov/building-participation/recruitment-retention) and to use evidence-informed practices for retention with the recognition that the variety of trainee backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with broader trainee retention efforts of the institution(s).

Institutional Environment and Commitment to Training

- The application should describe how the level of institutional and departmental commitment to research training will promote the success of the trainees and training program. This includes providing an inclusive, safe and supportive environment with procedures to ensure accountability and reporting of concerns. For institutions that have multiple NIH-funded training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones. A letter providing assurances of the institutional commitment should be provided in the Letters of Support section of the application. Detailed instructions on the types of support are found below in the Letters of Support section of the NOFO. Do not repeat information contained elsewhere in the application.

Training Outcomes

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for recent graduates in similar training to the proposed program). The application should provide the information below about recent outcomes through narrative descriptions and a summary of the data presented in the required training tables (https://grants.nih.gov/grants/forms/data-tables.htm) . The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications in Training Table 5 (https://grants.nih.gov/grants/forms/data-tables.htm), or other measures of scientific accomplishment appropriate to the field);
- The rate of program completion and length of training (for predoctoral trainees, explain how time-to-degree Training Table 8 (https://grants.nih.gov/grants/forms/data-tables.htm)).
- The success of recent graduates transitioning to careers in the biomedical research workforce (Training Table 8). (https://grants.nih.gov/grants/forms/data-tables.htm)

If disparities are observed in trainee outcomes, describe approaches to identify the causes and, where warranted, the approaches to feasibly address the issues in the Program Plan.

Progress Report for Renewal Applications

For renewal applications include information in the "Program Overview" section to demonstrate that the program successfully trained a diverse pool of

individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce. Highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program. Describe successes and challenges with implementation of the programmatic elements described in the previous application (e.g., curricular elements, mentor training activities, efforts to promote inclusive, safe, accessible and supportive research training environments) and provide justifications for failing to implement previously proposed programmatic elements. Include success rates for graduation and successful transitions to postdoc or careers in the biomedical research workforce and describe how the program made aggregate data on training and career outcomes publicly available.

Faculty, Trainees, and Training Record

Participating Faculty Biosketches

Program faculty are encouraged to provide a personal statement that describes their prior experience with:

- Training, mentoring, and promoting an inclusive and supportive scientific environment.
- Providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.
- Aiding and supporting trainees in identifying and transitioning into careers in the biomedical research workforce that are consistent with trainees' skills, interests, and values.

Letters of Support

Institutional Support Letter. The application must include a signed letter on institutional letterhead from a President, Provost, Dean or key institutional leader that describes the activities and resources provided by the institution that will ensure the success of the planned training program and the productivity of its trainees (not to exceed 10 pages). Institutional commitment to the following areas must also be described in the letter:

- Developing and promoting a culture in which the highest standards of scientific rigor, reproducibility and responsible conduct are advanced.
- Ensuring sufficient resources and support will be available to the training faculty and trainees, for example, to permit early stage faculty to participate in training and trainees to continue in training if their mentors experience a hiatus in research funding.
- Supporting core facilities and technology resources and describing how they can be used to enhance training.
- Providing adequate staff, facilities, and educational resources to the planned program.
- Supporting the PDs/PIs and other key staff associated with the planned training program; ensuring faculty have protected time available to devote to mentoring, training and research; considering activities integral to excellent training (such as teaching and mentorship) in tenure and promotion decisions.
- Promoting safe, accessible, and inclusive and supportive research training environments at all levels (trainees, staff, faculty, and leadership); ensuring the research facilities and laboratory practices promote the safety of trainees (see The NIH Grants Policy Statement Section 4 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm) regarding NIH recipient institutions expectations to provide safe and healthful working condition for their employees and foster work environments conducive to high-quality research); ensuring the research facilities are accessible to trainees with disabilities; ensuring a positive, supportive, and inclusive research and training environment for individuals from all backgrounds.
- Ensuring that proper policies, procedures, and oversight are in place to prevent discrimination, harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (see NOT-OD-20-124 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-124.html)).
- Providing the types and levels of support necessary for trainees to successfully complete the research training program.
- Supporting evaluation of the training program and procedures for responding to evaluation findings.

Other Training Program Section

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400); any instructions provided here are in addition to the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) instructions.

PHS Assignment Request Form

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm).

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120). The National Research Service Award (NRSA) policies (//grants.nih.gov/grants/guide/url_redirect.php?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost (//grants.nih.gov/grants/guide/url_redirect.php?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Requests of $500,000 or more for direct costs in any year

Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). Applicants are advised to refer to the Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/guide/contacts/PA-25-168.html) for exceptions.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 2 CFR 200.113 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and NIH Grants Policy Statement Section 4.1.35 (https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm).

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the HHS Office of Inspector Grant Self Disclosure Program (https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at grantdisclosures@oig.hhs.gov (mailto:grantdisclosures@oig.hhs.gov)

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.php?id=82299).

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system. While any information in the application relevant to the program goals can be included as part of the review process, the race, ethnicity, or sex (including gender identity, sexual orientation, or transgender status) of trainee candidates, trainees, or faculty may not, in and of themselves, be used as factors in the evaluation of applications.

For this particular NOFO, note the following: Reviewers should evaluate the program's potential to:

- Produce a pool of trainees with the technical, operational, and professional skills necessary to conduct rigorous and reproducible research, and transition into careers in the biomedical research workforce. Reviewers should note that careers in the biomedical research workforce refers to the breadth of careers that sustain the biomedical research enterprise (which includes, but is not exclusive to, careers as independent NIH-funded investigators).
- Enable research-oriented individuals from a wide range of backgrounds, including individuals from underrepresented groups, the ability to participate and succeed in the research training program (for example, through recruitment and mentor training activities).

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will equip the trainees with the skills, knowledge and experiences necessary to transition to successful careers in the biomedical research workforce, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed.)

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the training program and give a separate score for each. When applicable, the reviewers will consider relevant questions in the context of proposed short-term training. An application does not need to be strong in all categories to be judged likely to have major biomedical research training impact.

Training Program and Environment

- Does the application provide a compelling rationale for the proposed research training program and propose appropriate training goals and objectives relevant to the rationale?
- Will the courses, structured training activities, mentoring, and research experiences achieve the training program's goals and objectives, and provide opportunities for trainees to acquire skill and expertise in transparent, rigorous, reproducible and relevant research methodologies and tools applicable to the goals of the training program?
- Is there an effective mechanism to monitor mentoring and to promote the development, retention and success of all trainees throughout their training?
- Will the proposed training program provide the trainees appropriate information regarding the breadth of careers in the biomedical research workforce for which their training may be useful, and appropriate learning opportunities that allow them to develop the professional skills and networks necessary to transition into those careers?
- Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote

the success of the program?
- Is it clear how the proposed training program is distinguished from other externally funded training programs at the institution?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Do the PD(s)/PI(s) have the appropriate background, expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Do the PD(s)/PI(s) plan to commit sufficient effort to promote the program's success?
- Have the PD(s)/PI(s) demonstrated a strong commitment to training future researchers?
- Does the application describe how the PD(s)/PI(s) will receive appropriate training on effective mentoring practices to promote trainee success?
- **For applications designating multiple PDs/PIs:**
  - Is a strong justification provided that the multiple PD/PI leadership approach will benefit the training program and the trainees?
  - Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the training program and the complementary expertise of the PDs/PIs?

Preceptors/Mentors

- Does the proposed program demonstrate the presence of a sufficient pool of preceptors/mentors with appropriate expertise and adequate resources available to support the training goals and objectives proposed in the application (including short-term training, if applicable)?
- Is there a strong plan to ensure participating faculty receive appropriate training in the use of evidence-informed mentoring practices that promote the development of trainees from all backgrounds, including trainees from groups underrepresented in the biomedical sciences?
- Do participating faculty appropriately promote the trainees' career progression?

Trainees

- Does the proposed program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines and training stages to achieve the training program's objectives (including short-term training, if applicable)? Do the recruitment strategies identify trainee candidates with the potential to strongly benefit from, and with proper training and support, succeed in the training program?
- Does the program propose an appropriate multifactorial candidate review process to allow a broad group of research-oriented trainees the ability to participate in the training program (for example, a process that considers, consistent with applicable law, metrics beyond previous institution, GPA, and standardized test scores)?
- Are there well-defined and justified selection and re-appointment criteria?

Training Record

- How successful are the trainees (or, for new applications, recent graduates in similar training) in completing the program?
- Does the application provide evidence that trainees (or, for new applications, other recent graduates in similar training) conducted rigorous research that, appropriate to the training stage of the proposed program, advanced scientific knowledge and/or technologies with increasing self-direction (such as peer-reviewed publications and other accomplishments appropriate to the field)?
- How successful are the trainees (or, for new applications, recent graduates in similar training) in transitioning to careers in the biomedical research workforce that utilize their training and directly benefit the broader biomedical research enterprise?
- If disparities are observed in outcomes for trainees (or, for new applications, recent graduates in similar training), has the program proposed adequate approaches to identify the causes and, where warranted, approaches to feasibly address them?
- Does the program propose a rigorous evaluation plan to assess the effectiveness of the training program and the extent to which it is meeting its overall goals and objectives? Are effective mechanisms in place for obtaining feedback from current and former trainees, and appropriate plans to respond to trainee feedback?
- **For applications that request short-term research training positions,** is there a record of retaining health professional trainees in research training or other research activities for at least two years?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Recruitment Plan to Enhance Diversity

Reviewers will examine the strategies to be used in the recruitment of prospective candidates from underrepresented groups.

For purposes of this review, "recruitment" refers to outreach efforts intended to encourage individuals to apply for the program. "Recruitment" does not mean the appointment or hiring of an individual into the program. For renewals, the committee may consider the program's account of past experiences, including successful and unsuccessful strategies, but may not use the race, ethnicity, or sex of program trainees appointed during the previous funding period as factors in the evaluation.

Training in the Responsible Conduct of Research

All applications for support under this NOFO must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) ***Format -*** Does the plan satisfactorily address the format of instruction, e.g., lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (*A plan involving only on-line instruction is not acceptable.*); 2) ***Subject Matter –*** Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics? 3) ***Faculty Participation -*** Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) ***Duration of Instruction -*** Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) ***Frequency of Instruction –*** Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

For renewal applications, does the progress report document acceptable RCR instruction in the five components described above? Does the plan describe how participation in RCR instruction is being monitored? Are appropriate changes in the plan for RCR instruction proposed in response to feedback and in response to evolving issues related to responsible conduct of research?

Training in Methods for Enhancing Reproducibility

Does the plan for Instruction in Methods for Enhancing Reproducibility describe how the program will provide training in scientific reasoning, rigorous research design, relevant experimental methods, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, quantitative approaches, and data analysis and interpretation, appropriate to field of study and the level and prior preparation of the trainees?

For renewal applications, does the application document appropriate changes in the plan for Methods for Enhancing Reproducibility in response to feedback and to evolving issues related to the conduct of rigorous and reproducible research?

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

- Does the application describe the program's accomplishments over the past funding period(s)? Is the program achieving its training objectives?
- To what extent have the training goals and objectives been achieved since the last cycle? If certain goals were not met, did the program provide reasonable explanations and describe appropriate alternative approaches taken?
- Has the program evaluated the quality and effectiveness of the training experience (and when applicable, short-term training experience), and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are appropriate changes proposed that are likely to improve or strengthen the research training experience during the next project period (may not be applicable to short-term training)?
- Does the program use current, evidence-informed training and mentoring approaches and continue to evolve and reflect changes in the research area in which the training occurs?

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application

relates to a specific aspect of the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the sponsoring Institute or Center in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board.

The following will be considered in making funding decisions, consistent with applicable law:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement Section 2.5.1. Just-in-Time Procedures. (//grants.nih.gov/grants/guide/url_redirect.php?id=82418) This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access their Summary Statement (written critique) via the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the NIH Grants Policy Statement Section 5. The Notice of Award (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH Grants & Funding website, see Award Process. (https://grants.nih.gov/grants/pre-award-process.htm#award)

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at 2 CFR Part 200 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159).
- If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (HHS-690 (https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).
    - HHS recognizes that NIH research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm)

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See 2 CFR Part 200.340 Termination (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340) and NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support (https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions-_suspension__termination__and_withholding_of_support.htm).

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the NIH Grants Policy Statement - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=61170).

The taxability of stipends is described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=41171). Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=41171).

As specified in the NIH Revitalization Act of 1993, Kirschstein-NRSA recipients incur a service payback obligation for the first 12 months of postdoctoral support. Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=41171); and more details are in the Frequently Asked Questions (//grants.nih.gov/grants/guide/url_redirect.php?id=61174). Officials at the recipient institution have the responsibility of explaining the terms of the payback requirements to all prospective trainees before appointment to the training grant. Additionally, all trainees recruited into the training program should be provided with information related to the career options that might be available when they complete the program. The suitability of such career options as methods to satisfy the NRSA service payback obligation should be discussed.

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B) to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it (https://www.healthit.gov/topic/certification-ehrs/certification-health-it) to learn more.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework (https://www.nist.gov/cyberframework), to protect HHS systems and data. Please refer to NIH Post-Award Monitoring and Reporting (https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm) for additional information.

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data)

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the recipient institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award. The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=82420) for additional information on this reporting requirement.

Other Reporting Requirements

The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.php?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Recipients must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.php?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.

A final RPPR, the expenditure data portion of the Federal Financial Report, and Termination Notices for all Trainees, are required for closeout of an award as described in the NIH Grants Policy Statement Section 8.6 Closeout (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

5. Evaluation

In carrying out its stewardship of human resource-related programs, NIH may request information essential to an assessment of the effectiveness of

this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Because of the difference in individual Institute and Center (IC) program requirements for this NOFO, prospective applications **MUST** consult the **Table of IC-Specific Information, Requirements, and Staff Contacts**, to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten on-time submission, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (https://www.era.nih.gov/need-help) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application processes and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-480-7075

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contacts

See **Table of IC-Specific Information, Requirements and Staff Contacts** (https://grants.nih.gov/guide/contacts/PA-25-168.html)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contacts

See **Table of IC-Specific Information, Requirements and Staff Contacts** (https://grants.nih.gov/guide/contacts/PA-25-168.html)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.php?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 63A and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?11-15-24)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

NIH National Institutes of Health Office of Extramural Research (/grants/oer.htm)

(https://www.hhs.gov/) Department of Health and Human Services (HHS)

USA.gov (https://www.usa.gov/)

NIH... Turning Discovery Into Health®

A1067

EXHIBIT C

March 31, 2025

This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

Office of The Director, National Institutes of Health (OD (https://www.nih.gov/institutes-nih/nih-office-director))

National Eye Institute (NEI (https://www.nei.nih.gov/))

National Heart, Lung, and Blood Institute (NHLBI (https://www.nhlbi.nih.gov/))

National Human Genome Research Institute (NHGRI (https://www.genome.gov/))

National Institute on Aging (NIA (https://www.nia.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))

National Institute of Allergy and Infectious Diseases (NIAID (https://www.niaid.nih.gov/))

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS (https://www.niams.nih.gov/))

National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://www.nibib.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (https://www.nichd.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))

National Institute on Drug Abuse (NIDA (https://www.drugabuse.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

National Institute of General Medical Sciences (NIGMS (https://www.nigms.nih.gov/))

National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml))

National Institute of Nursing Research (NINR (https://www.ninr.nih.gov/))

National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))

Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP (https://orip.nih.gov/))

National Cancer Institute (NCI (https://www.cancer.gov/))

National Institute on Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/)), November 22, 2024 - Participation added (NOT-DK-25-007 (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-25-007.html))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of Research on Women's Health (ORWH (https://orwh.od.nih.gov/))

Office of Data Science Strategy (ODSS (https://datascience.nih.gov/about/odss))

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the ***Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/guide/contacts/PA-25-168.html)*** website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

Funding Opportunity Title

Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32)

Activity Code

T32 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t32&Search.x=0&Search.y=0&Search_Type=Activity) Institutional National Research Service Award (NRSA)

Announcement Type

Reissue of PA-23-048 (https://grants.nih.gov/grants/guide/pa-files/PA-23-048.html)

Related Notices

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=41857) associated with this funding opportunity

- **March 31, 2025** - This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.
- **December 10, 2024** - Notice of Correction to Eligibility Information and Application Instructions for the Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32) (PA-25-168). See Notice NOT-OD-25-036 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-25-036.html).
- **November 22, 2024** - Notice of NIDDK Participation in PA-25-168: "Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32)". See Notice NOT-DK-25-007 (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-25-007.html).
- **November 18, 2024** - Notice of Informational Webinar for NIGMS-Supported Postdoctoral Clinician-Scientists Institutional Training Programs (T32). See Notice NOT-GM-25-005 (//grants.nih.gov/grants/guide/notice-files/NOT-GM-25-005.html).

Funding Opportunity Number (FON)

PA-25-168

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.310, 93.313, 93.837, 93.233, 93.838, 93.839, 93.840, 93.286, 93.273, 93.213, 93.397, 93.396, 93.399, 93.398, 93.855, 93.351, 93.859, 93.361, 93.279, 93.113, 93.867, 93.172, 93.242, 93.866, 93.865, 93.846, 93.173, 93.847

Funding Opportunity Purpose

The National Institutes of Health (NIH) will award Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants (T32) to eligible, domestic institutions to develop and/or enhance predoctoral and postdoctoral research training, including short-term research training, to help ensure that a highly trained workforce is available to meet the needs of the Nation's biomedical, behavioral, and clinical research agenda. Research training programs are expected to incorporate engaging, didactic, research, and career development elements to prepare trainees for careers that will have a significant impact on the health-related research needs of the Nation. Programs proposing only short-term predoctoral research training should not apply to this announcement, but rather to the Kirschstein-NRSA Short-Term Institutional Research Training Grant Program (T35) exclusively reserved for predoctoral, short-term research training.

This Notice of Funding Opportunity (NOFO) does not allow Trainees to lead an independent clinical trial, but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Funding Opportunity Goal(s)

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

Key Dates

Posted Date

November 15, 2024

Open Date (Earliest Submission Date)

December 25, 2024

Letter of Intent Due Date(s)

Not Applicable

The following table includes NIH standard due dates (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
January 25, 2025 *	January 25, 2025 *	May 07, 2025 *	July 2025	October 2025	December 2025
May 25, 2025 *	May 25, 2025 *	September 07, 2025 *	November 2025	January 2026	April 2026
September 25, 2025 *	September 25, 2025 *	January 07, 2026 *	March 2026	May 2026	July 2026
January 25, 2026 *	January 25, 2026 *	May 07, 2026 *	July 2026	October 2026	December 2026
May 25, 2026 *	May 25, 2026 *	September 07, 2026 *	November 2026	January 2027	April 2027
September 25, 2026 *	September 25, 2026 *	January 07, 2027 *	March 2027	May 2027	July 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	October 2027	December 2027
May 25, 2027 *	May 25, 2027 *	September 07, 2027 *	November 2027	January 2028	April 2028
September 25, 2027 *	September 25, 2027 *	January 07, 2028 *	March 2028	May 2028	July 2028

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date

May 05, 2028

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Training (T) Instructions in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed to do otherwise (in this NOFO or in a Notice from the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/url_redirect.php?id=11164)). Conformance to all requirements (both in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400), follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-168) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (https://researchtraining.nih.gov/programs/training-grants/T32-a) (NRSA) website.

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Institutional NRSA programs allow the Training Program Director/Principal Investigator (Training PD/PI) to select trainees and

develop an enhanced program of coursework, mentored research experiences, and technical, operational and professional skills development that provides added value to already existing programs and prepares the appointed trainees for careers in the biomedical research workforce (the breadth of careers that sustain the biomedical research enterprise, including but limited to careers as independent NIH-funded investigators).

The grant offsets the costs of stipends, tuition and fees, and training related experiences, including health insurance, for the appointed trainees in accordance with the approved NIH support levels. The proposed institutional research training program may complement other ongoing research training and career development programs at the applicant organization but must be clearly distinct from related program currently receiving Federal support.

Purpose

The purpose of the Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (T32) program is to develop and/or enhance research training opportunities for individuals interested in careers in biomedical, behavioral or social sciences, and clinical research, in health services research, or in any other discipline relevant to the NIH mission. NIH encourages biomedical research training to keep pace with the rapid evolution of the biomedical research enterprise that is increasingly complex, interdisciplinary, quantitative, and collaborative. Programs should prepare trainees to effectively engage in a research enterprise characterized by increased breadth in the approaches taken to investigate research questions, and the range of careers that biomedical doctoral recipients are pursuing. There is also increasing recognition of the need to enhance the reproducibility of biomedical research results through scientific rigor and transparency, and the skills of mentors to effectively engage the 21st century trainee population.

Each proposed program should provide rigorous research training, and mentored research experiences, and are expected to help trainees develop:

- The skills to independently acquire the knowledge needed to advance their chosen field;
- The ability to think critically and independently, and to identify important research questions and approaches that push forward the boundaries of their areas of study;
- An understanding of the health-related sciences and the relationship of their research training to health and disease;
- A strong foundation in scientific reasoning, rigorous and reproducible research design, experimental methods, quantitative and computational approaches, and data analysis and interpretation;
- The skills to conduct research in the safest manner possible, and a commitment to approaching biomedical research responsibly, ethically, and with integrity;
- Experience initiating, conducting, interpreting and presenting rigorous and reproducible research with increasing self-direction;
- The ability to work effectively in teams with colleagues from a variety of scientific backgrounds and to promote the development of safe and supportive scientific research environments;
- The skills to teach and communicate scientific research methodologies and findings to a wide variety of audiences (e.g., discipline-specific, across disciplines, and the public); and
- The knowledge, professional skills, and experiences required to identify and transition into careers in the biomedical research workforce.

Program Considerations

This NOFO is intended to support rigorous research training programs that will promote the development of a biomedical research workforce that will benefit from the full range of skills and experiences needed to advance and translate discovery for the benefit of all. Consistent with existing NIH practices and applicable law: (1) Funded programs may not use the race, ethnicity, or sex of a trainee or faculty candidate as an eligibility or selection criteria, and (2) NIH does not use the race, ethnicity, or sex of trainee candidates, trainees, or faculty in the application review process or funding decisions. Applicants and award recipients are encouraged to consult with their General Counsel to ensure all applicable laws and regulations are being followed in program design and implementation.

Applicants are expected to identify unique training goals and objectives (i.e., specific and measurable outcomes the program intends to achieve) and develop plans to implement evidence-informed training and mentoring activities (i.e., approaches that are grounded in the literature and from evaluations of existing relevant training programs) to address those needs and objectives.

Safe and Supportive Research Training Environments that Promote Scientific Rigor

Funded programs are expected to implement robust plans to develop safe and supportive research training environments to maximize success for all individuals in the training program. Specifically, funded programs should have institutional and departmental environments where all individuals are integrated into and supported by the biomedical research community. Funded programs are also expected to implement plans to enhance trainee retention (i.e., to sustain the scientific interests and participation of trainees from all backgrounds), which may be integrated with plans for mentor training (see below). Safety in research training environments should encompass:

- Environments free from harassment, bullying and intimidation (https://grants.nih.gov/grants/policy/harassment.htm), in which everyone participating is treated in a respectful and supportive manner,
- Laboratory and clinical settings where individuals exercise the highest standards of practice for chemical, biological and physical safety (for more information see examples of Laboratory Safety Training Guidelines (https://nigms.nih.gov/training/Pages/Laboratory-Safety-Training-and-Guidelines.aspx)), and
- Practices at the institutional leadership and research community levels that demonstrate core values and behaviors to emphasize safety over competing goals.

Biomedical research and the resulting scientific knowledge are increasingly complex, multidisciplinary, and collaborative in nature. Training PDs/PIs are encouraged to develop institutional training programs that will provide trainees with education and experience in a variety of rigorous and reproducible scientific approaches, systems for study, tools, and technologies. Consideration of team-based research approaches may also be

warranted depending upon the goals of the proposed training program. Funded training programs must ensure that trainees have a solid foundation in methods to enhance data reproducibility through rigor and transparency (for examples, see NIH Rigor and Reproducibility Training (https://www.nih.gov/research-training/rigor-reproducibility/training)).

Mentor Training

Effective mentorship is critical to the development and retention of scientists and the advancement of research. Studies have shown that effective mentorship has overall positive effects on mentees, mentors and the overall research environment (e.g., improved academic achievement, retention, and degree attainment, career satisfaction, career commitment). Formal training, and ongoing professional development in effective mentoring practices has been shown to improve the knowledge and skills of research mentors across career stages.

Funded training programs are expected to support effective mentorship by ensuring all program faculty complete formal mentor training and periodic refreshers. Programs should consider the following as potential mentor training components, and are encouraged to adapt to program and trainee needs:

- Aligning expectations.
- Maintaining effective communication.
- Fostering independence.
- Assessing understanding.
- Enhancing professional development.
- Articulating a mentoring philosophy and plan.

Trainee Career Development

Scientists supported by NRSA training programs pursue a variety of careers in the biomedical research workforce in various sectors. These include research-intensive careers in academia, industry and government, and research-related careers in academic institutions, government agencies, for-profit businesses, and private foundations that directly benefit the broader biomedical research enterprise. Training PDs/PIs should make available appropriate skills training so that trainees are prepared to apply for subsequent independent support for their training, career development or research program (e.g., an individual fellowship award, mentored career development award, or research project grant), as appropriate for their career stage and interest. Training programs should also make available structured career development opportunities (e.g., workshops, individual development plans, informational interviews, shadowing, internships) so that trainees will obtain a working knowledge of various potential career paths that would make strong use of the knowledge and skills gained during research training, and the steps, experiences, networks, and credentials required to transition successfully to the next stage of their chosen career.

Considerations for Clinicians and Dual-degree Students

Past studies have shown that health professional trainees who train in programs with postdoctoral researchers who have intensive research backgrounds are more likely to work with their institutions to apply for and receive subsequent research grant support. Programs that emphasize research training for individuals with the MD or other health-professional degrees are therefore encouraged to develop interactions with basic science departments and include trainees with research doctorates when this approach is consistent with the goals of the proposed training program.

Institutional research training grants must be used to support a program of full-time research training. Within the full-time training period, research trainees who are also training as clinicians must devote their time to the proposed research training and confine clinical duties to those that are an integral part of the research training experience or can be conducted in the allowable additional 25% of their time (e.g., 10 hours per week) that may be devoted to clinical employment. The program may not be used to support studies leading to the MD, DDS, or other clinical, health-professional degrees except when those studies are part of a formal combined research degree program, such as the MD/PhD. Similarly, trainees may not accept NRSA support for clinical training that is part of residency training leading to clinical certification in a medical or dental specialty or subspecialty. It is permissible and encouraged, however, for clinicians to engage in NRSA-supported, full-time postdoctoral research training even when that experience is creditable toward certification by a clinical specialty or subspecialty board.

Other Considerations

Institutional commitment and support for the proposed training program are important elements of the application. The research training program may complement and synergize with other ongoing federally supported research training and career development programs at the applicant institution (e.g., in the development of skills needed for careers in the biomedical research workforce that are not discipline-specific); however, the research training goals and objectives must be distinct from related programs at the same institution currently receiving federal support. Funded programs are expected to provide evidence of accomplishing the training goals in progress reports and upon renewal, to make aggregate data on training and career outcomes publicly available, and are strongly encouraged to disseminate successful training practices to the broader training community. Training grant funds may not be used solely as a vehicle to provide stipends for trainees to conduct research.

The duration of training, the transition of trainees to individual support mechanisms, and their transition to the next career stage are important considerations in institutional training programs. Also, an important consideration is the engagement of trainees in their training goals, process and activities through the program that enhances what they may be getting in existing programs within the institution. Training PD/PIs should limit appointments to individuals who plan to remain in the training program for no less than two years, whether that support comes from a training grant or some combination of NRSA and non-NRSA programs institution.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training. Short-term positions should be requested at the time of application, as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11.1_general.htm). Research training programs solely for short-term research training

should not apply to this announcement, but rather the T35 NRSA NOFO, which can be found in the NIH Training Kiosk. (https://researchtraining.nih.gov/programs/training-grants)

This Notice of Funding Opportunity (NOFO) does not support of Trainees to lead an independent clinical trial, but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this NOFO, prospective applicants **MUST** consult the **Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/guide/contacts/PA-25-168.html)**, to make sure that their application is appropriate for the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Renewal
Resubmission
Revision

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited, but need to reflect the actual needs of the proposed project.

Recipients are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (*NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards for T32 institutional NRSA research training grants may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Ruth L. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

Travel for trainees to attend scientific meetings and workshops that the institution determines to be necessary for the individual's research training experience is an allowable expense for predoctoral and postdoctoral trainees. This includes trainees on short-term appointments. Trainees must be appointed to the training grant at the time of the actual travel for this to be an allowable cost.

The amount of funds provided for trainee travel may vary by NIH Institute or Center; applicants are encouraged to consult the Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/guide/contacts/PA-25-168.html) for further information.

Training Related Expenses

NIH will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, mentor training activities, equipment, research supplies, and faculty/staff travel directly related to the research training program. The most recent levels of training related expenses are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of $25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Local Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information.

- System for Award Management (SAM) (https://grants.nih.gov/grants/guide/url_redirect.php?id=82390) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with their organization to develop an application for support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy (//grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

The PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be responsible for the selection and appointment of trainees to the approved research training program, and for the overall direction, management, administration, and evaluation of the program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required. The PD/PI has responsibility for the day-to-day administration of the program and is responsible for appointing members of the Advisory Committee (when applicable), using their recommendations to determine the appropriate allotment of funds. Additional PDs/PIs, including individuals with experience in areas relevant to the program goals may be included to achieve the training goals.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement Section 1.2 Definition of Terms (//grants.nih.gov/grants/guide/url_redirect.php?id=11126).

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is programmatically distinct.

NIH will not accept duplicate or highly overlapping applications under review at the same time per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//grants.nih.gov/grants/guide/url_redirect.php?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.

- An application that has substantial overlap with another application pending appeal of initial peer review (see NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423))

Preceptors/Mentors

Program faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support in the area of the proposed research training program. Programs are encouraged to recruit prospective preceptors/mentors and faculty with relevant experience and expertise to advance the program goals, including faculty at different career stages (for example, early stage investigators as well as senior faculty). When building a training team, programs should include faculty who are committed to training, mentoring, and providing safe and supportive research training environments. All program faculty should have a mentoring philosophy appropriately tailored to the needs of potential trainees that ensures trainees will receive the tailored mentorship needed to develop skills and advance their career. Program faculty should also have sufficient time to commit to training given their other professional obligations.

Trainees

The applicant organization will select the trainees to be supported by the research training program and is responsible for establishing trainee eligibility and selection criteria that are consistent with applicable law.

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the awarding unit, or when trainees are appointed to approved, short-term training positions.

Predoctoral trainees. Predoctoral trainees must be enrolled in a program leading to a PhD or in an equivalent research doctoral degree program. Health-professional students who wish to interrupt their studies for a year or more to engage in full-time research training before completing their formal training programs, are also eligible.

Postdoctoral trainees. Postdoctoral trainees must have received, as of the beginning date of the NRSA appointment, a Ph.D., M.D., D.D.S., or comparable doctoral degree from an accredited domestic or foreign institution. Comparable doctoral degrees include, but are not limited to, the following: D.M.D., DC, DO, DVM., OD, DPM, ScD, EngD, DrPH, DNSc, DPT, PharmD, ND (Doctor of Naturopathy), DSW, PsyD, as well as a doctoral degree in nursing research. Documentation by an authorized official of the degree-granting institution certifying all degree requirements have been met prior to the beginning date of the training appointment is acceptable. Individuals in postgraduate clinical training, who wish to interrupt their studies for a year or more to engage in full-time research training before completing their formal training programs, are also eligible.

Short-term trainees.

Trainees selected for short-term training are required to pursue research training for 2-3 months on a full-time basis devoting at least 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Within the full-time training period, trainees must devote their time to the proposed research training and must confine clinical duties to those that are an integral part of the research training experience. Successful trainees may be appointed for additional periods of short-term training or, if appropriate to their career level, they should be encouraged to apply for an extended period of full-time training supported by an NRSA training grant or fellowship, or an NIH career development award.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training.

Short-term trainees must be medical students, dental students, students in other health-professional programs, or graduate students in the physical or quantitative sciences. To be eligible for short-term, predoctoral research training positions students must be enrolled, in good standing, and must have completed at least one quarter or semester in a program leading to a clinical doctorate or a doctorate in a physical or quantitative science such as physics, mathematics, or engineering before participating in the training program. Individuals already matriculated in a formal research degree program in the health sciences, or those holding a research doctorate, a master's degree, or a combined health-professional/research doctorate normally are not eligible for short-term training positions. Within schools of pharmacy, only individuals who are candidates for the PharmD degree are eligible for short-term, research training positions.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Training (T) Instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.php?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424 (R&R) Other Project Information

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Project Summary/Abstract. Provide an abstract of the entire application. Include the goals, objectives, rationale and design of the research training/career development program, as well as key activities in the training plan. Indicate the planned duration of appointments, the projected number of trainees/scholars including their levels (i.e., predoctoral, postdoctoral, short-term), and intended trainee/scholar outcomes.

Other Attachments. An Advisory Committee is not a required, but a highly recommended component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training program. The composition, roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee members should be named in the application if they have been invited to participate at the time the application is submitted. Renewal applications with Advisory Committees should include the names of all committee members during the past project period. Please name your file "Advisory_Committee.pdf".

The filename provided for each "Other Attachment" will be the name used for the bookmark in the electronic application in eRA Commons.

SF424(R&R) Senior/Key Person Profile Expanded

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

PHS 398 Cover Page Supplement

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Training Budget

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) with the following additional modifications:

- Include all personnel other than the Training PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.

PHS 398 Research Training Program Plan

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program
- Faculty, Trainees, and Training Record
- Other Training Program
- Appendix - Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the NOFO specifically instructs applicants to do so.

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

The following modifications apply:

Particular attention must be given to the required **Training Data Tables** (//grants.nih.gov/grants/guide/url_redirect.php?id=61169). Applicants should summarize, in the body of the application, key data from the tables that highlight the characteristics of the prospective candidate pool, faculty mentors, the educational and career outcomes of past participants, and other factors that contribute to the overall environment of the program.

Training Program

In addition to the information specified in the Application Guide, describe the following for each section of the Program Plan attachment:

Background

The application should clearly describe the goals (i.e., broad statement of purpose of the program), and objectives (i.e., specific measurable outcomes the program intends to achieve) of the proposed research training program. The program-specific goals and objectives should align with the Program Objective of this funding announcement while focusing on developing the specific skills required to be a well-trained scientist in the proposed scientific discipline(s).

The application should describe how the program will develop a pool of well-trained scientists who have the technical, operational, and professional skills required to conduct research in a safe, ethically responsible and rigorous manner, and to enter careers in the biomedical research workforce as delineated in the Program Objective. The application should describe how the program will enhance the training environment and not simply provide financial support to trainees.

Program Plan

Program Administration (Training Program Director(s)/Principal Investigator(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PDs/PIs) will promote the success of the trainees and training program. Multiple PDs/PIs are encouraged, particularly when each brings a unique skill set that will enhance training. The application should expand on the information in the biosketch(es) to address how the PD/PI or PD/PI team has:

- The appropriate expertise (for example, a record of rigorous research), as well as the administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program.
- The time to commit sufficient effort to ensure the program's success, given other professional obligations (applicants should indicate the program director's percent effort in the proposed program).
- A demonstrated commitment to training future biomedical research researchers.
- Received training (or have a plan in place to ensure they receive training) on how to effectively mentor the entire trainee pool prior to the start of the program.

This section should describe how previous mentoring experiences of the PD(s)/PI(s) will support the success of the proposed training program.

Program Faculty

The application should describe (a) the faculty participants and (b) planned mentor training and oversight.

Faculty Participants, please describe:

- The efforts made to recruit a pool of prospective program faculty from various career stages with relevant experience and expertise to advance the program goals to enhance the training environment.

Mentor Training and Oversight, please describe:

- The planned strategy and administrative structure to oversee and monitor the program and ensure appropriate and timely trainee progress. This should include a mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty who continue to display unacceptable mentorship qualities from the training program.
- How the participating faculty are trained to ensure the use of evidence-informed mentoring practices that promote the development of all trainees. Include the planned format, duration, and frequency of mentor training activities for program faculty and a description of how mentor training has been tailored to the goals and objectives of the broader training program. Describe the major topics covered in mentor training. Examples of relevant topics include, but are not limited to:
    - Aligning expectations.
    - Maintaining effective communication.
    - Fostering independence.
    - Assessing scholars' understanding of scientific research.
    - Enhancing professional development.
    - Articulating your mentoring philosophy and plan.

Proposed Training

In addition to the information specified in the Application Guide, describe:

- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, and professional development, and how these activities will address the program's training goals and objectives.
- How trainees will be instructed on data science principles that are relevant to their areas of research. Examples include statistics, computational science, bioinformatics, data sharing and access, data management, data security, and data privacy in human subjects research.

Career Development

The proposed training should include a section on career development activities for trainees involved in the program, and should describe:

- How the pool of potential applicants and trainees will be provided with information about the overall biomedical research workforce employment landscape, the variety of careers in the biomedical research workforce for which their training would be useful, and the career outcomes of graduates of the program (e.g., on publicly accessible websites).
- How the proposed program will engage a range of potential employers to ensure the trainees will acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them and consistent with their values.

- How the training program or institution will provide appropriate experiential learning opportunities (e.g., internships, shadowing, informational interviews, teaching opportunities) that allow trainees to develop the professional skills and networks necessary to transition into careers in the biomedical research workforce.

Training Program Evaluation

The application should describe:

- How the proposed evaluation will assess the extent to which the overall program is effective in meeting its training goals and objectives, and whether the research training environment is supportive of trainee development .
- The program's procedures for responding to program evaluation findings.

Trainee Candidates and Retention Plans

Through the narrative and summaries of the information presented in the Training Data Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and the attachments, the application should:

- Provide a strong justification for the number of requested trainee positions.
- Describe a multifactorial candidate review process (i.e., a process that considers metrics beyond previous institution, GPA, and standardized test scores) that will allow research-oriented trainees who have taken advantage of the research opportunities available to them and are committed to contributing to the biomedical research enterprise the ability to participate in the training program. Programs are encouraged to consider individuals who have the potential to strongly benefit from, and with proper training and support, succeed in the program (see also, Program Considerations in section I above).

Retention Plans

Describe efforts to sustain the scientific interests as well as monitor the academic and research progress of trainees from all backgrounds within the program (i.e., retention). Applicants are encouraged to use evidence-informed practices for retention with the recognition that the variety of trainee educational backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with broader trainee retention efforts of the institution(s).

Institutional Environment and Commitment to Training

- The application should describe how the level of institutional and departmental commitment to research training will promote the success of the trainees and training program. This includes providing a safe and supportive research training environment with procedures to ensure accountability and reporting of concerns. For institutions that have multiple NIH-funded training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones. A letter providing assurances of the institutional commitment should be provided in the Letters of Support section of the application. Detailed instructions on the types of support are found below in the Letters of Support section of the NOFO. Do not repeat information contained elsewhere in the application.

Training Outcomes

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for recent graduates in similar training to the proposed program). The application should provide the information below about recent outcomes through narrative descriptions and a summary of the data presented in the required training tables (https://grants.nih.gov/grants/forms/data-tables.htm) . The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications in Training Table 5 (https://grants.nih.gov/grants/forms/data-tables.htm), or other measures of scientific accomplishment appropriate to the field);
- The rate of program completion and length of training (for predoctoral trainees, explain how time-to-degree Training Table 8 (https://grants.nih.gov/grants/forms/data-tables.htm)).
- The success of recent graduates transitioning to careers in the biomedical research workforce (Training Table 8). (https://grants.nih.gov/grants/forms/data-tables.htm)

If disparities are observed in trainee outcomes, describe approaches to identify the causes and, where warranted, the approaches to feasibly address the issues in the Program Plan.

Progress Report for Renewal Applications

For renewal applications include information in the "Program Overview" section to demonstrate that the program successfully trained a pool of individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce. Highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program. Describe successes and challenges with implementation of the programmatic elements described in the previous application (e.g., curricular elements, mentor training activities, efforts to promote safe and supportive research training environments) and provide justifications for failing to implement previously proposed programmatic elements. Include success rates for graduation and successful transitions to postdoc or careers in the biomedical research workforce and describe how the program made aggregate data on training and career outcomes publicly available.

Faculty, Trainees, and Training Record

Program faculty are encouraged to provide a personal statement that describes their prior experience with:

- Training, mentoring, and promoting a supportive scientific environment.
- Providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.
- Aiding and supporting trainees in identifying and transitioning into careers in the biomedical research workforce that are consistent with trainees' skills, interests, and values.

Letters of Support

Institutional Support Letter. The application must include a signed letter on institutional letterhead from a President, Provost, Dean or key institutional leader that describes the activities and resources provided by the institution that will ensure the success of the planned training program and the productivity of its trainees (not to exceed 10 pages). Institutional commitment to the following areas must also be described in the letter:

- Developing and promoting a culture in which the highest standards of scientific rigor, reproducibility and responsible conduct are advanced.
- Ensuring sufficient resources and support will be available to the training faculty and trainees, for example, to permit early stage faculty to participate in training and trainees to continue in training if their mentors experience a hiatus in research funding.
- Supporting core facilities and technology resources and describing how they can be used to enhance training.
- Providing adequate staff, facilities, and educational resources to the planned program.
- Supporting the PDs/PIs and other key staff associated with the planned training program; ensuring faculty have protected time available to devote to mentoring, training and research; considering activities integral to excellent training (such as teaching and mentorship) in tenure and promotion decisions.
- Promoting safe and supportive research training environments at all levels (trainees, staff, faculty, and leadership); ensuring the research facilities and laboratory practices promote the safety of trainees (see The NIH Grants Policy Statement Section 4 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm) regarding NIH recipient institutions expectations to provide safe and healthful working condition for their employees and foster work environments conducive to high-quality research.
- Ensuring that proper policies, procedures, and oversight are in place to prevent discrimination, harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (see NOT-OD-20-124 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-124.html)).
- Providing the types and levels of support necessary for trainees to successfully complete the research training program.
- Supporting evaluation of the training program and procedures for responding to evaluation findings.

Other Training Program Section

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400); any instructions provided here are in addition to the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) instructions.

PHS Assignment Request Form

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm).

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120). The National Research Service Award (NRSA) policies (//grants.nih.gov/grants/guide/url_redirect.php?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost (//grants.nih.gov/grants/guide/url_redirect.php?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Requests of $500,000 or more for direct costs in any year

Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). Applicants are advised to refer to the Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/guide/contacts/PA-25-168.html) for exceptions.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 2 CFR 200.113 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and NIH Grants Policy Statement Section 4.1.35 (https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm).

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the HHS Office of Inspector Grant Self Disclosure Program (https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at grantdisclosures@oig.hhs.gov (mailto:grantdisclosures@oig.hhs.gov)

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.php?id=82299).

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Trainees

- Does the proposed program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines and training stages to achieve the training program's objectives (including short-term training, if applicable)? Do the recruitment strategies identify trainee candidates with the potential to strongly benefit from, and with proper training and support, succeed in the training program?
- Does the program propose an appropriate multifactorial candidate review process to allow a broad group of research-oriented trainees the ability to participate in the training program (for example, a process that considers, consistent with applicable law, metrics beyond previous institution, GPA, and standardized test scores)?
- Are there well-defined and justified selection and re-appointment criteria?

Training Record

- How successful are the trainees (or, for new applications, recent graduates in similar training) in completing the program?
- Does the application provide evidence that trainees (or, for new applications, other recent graduates in similar training) conducted rigorous research that, appropriate to the training stage of the proposed program, advanced scientific knowledge and/or technologies with increasing self-direction (such as peer-reviewed publications and other accomplishments appropriate to the field)?
- How successful are the trainees (or, for new applications, recent graduates in similar training) in transitioning to careers in the biomedical research workforce that utilize their training and directly benefit the broader biomedical research enterprise?
- If disparities are observed in outcomes for trainees (or, for new applications, recent graduates in similar training), has the program proposed adequate approaches to identify the causes and, where warranted, approaches to feasibly address them?
- Does the program propose a rigorous evaluation plan to assess the effectiveness of the training program and the extent to which it is meeting its overall goals and objectives? Are effective mechanisms in place for obtaining feedback from current and former trainees, and appropriate plans to respond to trainee feedback?
- **For applications that request short-term research training positions,** is there a record of retaining health professional trainees in research training or other research activities for at least two years?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Training in the Responsible Conduct of Research

All applications for support under this NOFO must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) ***Format -*** Does the plan satisfactorily address the format of instruction, e.g., lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (*A plan involving only on-line instruction is not acceptable.*); 2) ***Subject Matter –*** Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics? 3) ***Faculty Participation -*** Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) ***Duration of Instruction -*** Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) ***Frequency of Instruction –*** Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

For renewal applications, does the progress report document acceptable RCR instruction in the five components described above? Does the plan describe how participation in RCR instruction is being monitored? Are appropriate changes in the plan for RCR instruction proposed in response to feedback and in response to evolving issues related to responsible conduct of research?

Training in Methods for Enhancing Reproducibility

Does the plan for Instruction in Methods for Enhancing Reproducibility describe how the program will provide training in scientific reasoning, rigorous research design, relevant experimental methods, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, quantitative approaches, and data analysis and interpretation, appropriate to field of study and the level and prior preparation of the trainees?

For renewal applications, does the application document appropriate changes in the plan for Methods for Enhancing Reproducibility in response to feedback and to evolving issues related to the conduct of rigorous and reproducible research?

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

- Does the application describe the program's accomplishments over the past funding period(s)? Is the program achieving its training objectives?
- To what extent have the training goals and objectives been achieved since the last cycle? If certain goals were not met, did the program provide reasonable explanations and describe appropriate alternative approaches taken?
- Has the program evaluated the quality and effectiveness of the training experience (and when applicable, short-term training experience), and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are appropriate changes proposed that are likely to improve or strengthen the research training experience during the next project period (may not be applicable to short-term training)?
- Does the program use current, evidence-informed training and mentoring approaches and continue to evolve and reflect changes in the research area in which the training occurs?

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific aspect of the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the sponsoring Institute or Center in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board.

The following will be considered in making funding decisions, consistent with applicable law:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement Section 2.5.1. Just-in-Time Procedures. (//grants.nih.gov/grants/guide/url_redirect.php?id=82418) This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access their Summary Statement (written critique) via the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the NIH Grants Policy Statement Section 5. The Notice of Award (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH Grants & Funding website, see Award Process. (https://grants.nih.gov/grants/pre-award-process.htm#award)

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at 2 CFR Part 200 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159).
- If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (HHS-690 (https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).
    - HHS recognizes that NIH research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm)

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See 2 CFR Part 200.340 Termination (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340) and NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support (https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions-_suspension__termination__and_withholding_of_support.htm).

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the NIH Grants Policy Statement - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=61170).

The taxability of stipends is described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=41171). Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=41171).

As specified in the NIH Revitalization Act of 1993, Kirschstein-NRSA recipients incur a service payback obligation for the first 12 months of postdoctoral support. Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=41171); and more details are in the Frequently Asked Questions (//grants.nih.gov/grants/guide/url_redirect.php?id=61174). Officials at the recipient institution have the responsibility of explaining the terms of the payback requirements to all prospective trainees before appointment to the training grant. Additionally, all trainees recruited into the training program

should be provided with information related to the career options that might be available when they complete the program. The suitability of such career options as methods to satisfy the NRSA service payback obligation should be discussed.

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B) to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it (https://www.healthit.gov/topic/certification-ehrs/certification-health-it) to learn more.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework (https://www.nist.gov/cyberframework), to protect HHS systems and data. Please refer to NIH Post-Award Monitoring and Reporting (https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm) for additional information.

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data)

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the recipient institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award. The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=82420) for additional information on this reporting requirement.

Other Reporting Requirements

The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.php?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Recipients must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.php?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.

A final RPPR, the expenditure data portion of the Federal Financial Report, and Termination Notices for all Trainees, are required for closeout of an award as described in the NIH Grants Policy Statement Section 8.6 Closeout (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must

also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

5. Evaluation

In carrying out its stewardship of human resource-related programs, NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Because of the difference in individual Institute and Center (IC) program requirements for this NOFO, prospective applications **MUST** consult the **Table of IC-Specific Information, Requirements, and Staff Contacts**, to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten on-time submission, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (https://www.era.nih.gov/need-help) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application processes and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-480-7075

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contacts

See **Table of IC-Specific Information, Requirements and Staff Contacts** (https://grants.nih.gov/guide/contacts/PA-25-168.html)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contacts

See **Table of IC-Specific Information, Requirements and Staff Contacts** (https://grants.nih.gov/guide/contacts/PA-25-168.html)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.php?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 63A and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?11-15-24)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

National Institutes of Health (/grants/oer.htm)
Office of Extramural Research

(https://www.hhs.gov/) Department of Health and Human Services (HHS)

USA.gov (https://www.usa.gov/)

NIH... Turning Discovery Into Health®

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)

DECLARATION OF APHA MEMBER 1

I, [redacted], pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. I am a Professor of Epidemiology at a private university in Massachusetts, where I have been a member of the faculty since 1995.

2. I earned my Ph.D. in Epidemiology from the University of California, Berkeley, in 1989. My academic background also includes training in biochemistry, philosophy of science, and the history of public health. Over the past thirty-five years, I have engaged in scientific research that furthers my longstanding commitment to social justice and public health.

3. My work centers on using etiologic and methodologic research to improve population health, with a strong focus on understanding the societal determinants of health inequities to advance health justice. I have studied the complex intersections between racism, social class, and health in the United States. Grounded in theoretical frameworks such as ecosocial theory, my

research explores how social and environmental conditions shape health outcomes across populations. I also develop innovative methods to better monitor and address health inequities, aiming to inform more equitable and effective public health policies and practices.

4. I am an internationally recognized social epidemiologist and a [redacted]. My honors include the [redacted].

5. I have served as Principal Investigator on multiple National Institutes of Health ("NIH") funded grants focused on structural determinants of health and methodological innovation. These include: a five-year grant investigating how social adversity affects DNA methylation and contributes to health inequities; a five-year grant to develop improved tools to measure multiple forms of discrimination and assess their impact on population health; two three-year grants which examined disparities in breast cancer tumor biology and outcomes; a three-year grant which analyzed the enduring health impacts of Jim Crow laws using age-period-cohort methods. These projects reflect my research into the social and structural causes of health inequities and the development of methods to study them.

6. I am offering this Declaration in my individual capacity and not on behalf of my employer.

7. I am a member of the American Public Health Association, and I pay $225 in annual dues.

8. On June 19, 2019, in support of my research, my institution was awarded a five-year, $4 million R01 grant from the National Institute on Minority Health and Health Disparities ("NIMHD") to develop time-efficient tools for assessing patients' experiences of discrimination based on race, gender, gender identity, sexual orientation, age, and weight. The project, titled [redacted], was motivated by concerns that existing approaches significantly underestimate the impact of discrimination on population health. A true and correct copy of my Notice of Award for this grant is attached as Exhibit A.

9. This project builds on my prior research using both explicit self-report measures and implicit tools, including earlier and updated versions of the Implicit Association Test, a timed reaction test designed to reveal unconscious associations of ideas, including but not limited to

biases. Prior studies—some conducted in collaboration with Boston community health centers—focused on implicit and explicit exposures to discrimination but left key questions unanswered. This new grant-supported project incorporates contemporary methods to compare implicit and explicit approaches across a broader range of discrimination types, aiming to improve the accuracy and efficiency of assessment in clinical settings.

10. The study was conducted at three federally qualified community health centers in Boston, Massachusetts and involved 699 randomly selected adult participants. It used both a refined Implicit Association Test to measure participants' unconscious awareness of being a target of six types of discrimination and a validated self-report survey to assess lifetime exposure to six types of discrimination; these types of discrimination involve: race/ethnicity, gender, gender identity, age, sexual orientation, and weight. Participants also completed standardized assessments of psychological distress and sleep-related health outcomes, including insufficient sleep and sleep-disordered breathing. The goal of the project was to evaluate the effectiveness of combining implicit and explicit tools to more accurately capture exposure to discrimination and its impacts on health. By applying causal mediation analyses, the study aimed to identify which types and combinations of discrimination most strongly mediate health inequities.

11. This project was staffed by over fifteen people, including the Principal Investigator, two co-investigator epidemiologists, the project director, a biostatistician, a social psychologist, a data analyst, a clinic's medical director, a clinic consortium's director and staff member, and numerous research assistants, graduate students, and undergraduate students.

12. Initiated by a federal grant awarded in June 2019, the project was the result of four years of intensive effort. The application itself required significant preparation, including a comprehensive review of the background literature, development of the experimental design, pilot tests, and the assembly and refinement of detailed application materials. The team submitted the proposal to NIH and subsequently revised it based on reviewer feedback to ensure alignment with agency expectations. Once funded, and despite a compressed first year of support, the team fully developed the study infrastructure, including survey design, recruitment protocols, and operational systems. The project was poised to go into the field to recruit participants in March 2020, but the onset of the COVID-19 pandemic at that time and the subsequent lockdowns necessitated an immediate pivot to remote implementation. This required substantial additional effort to redesign

communication systems and study procedures, particularly in collaboration with community health partners serving populations hardest hit by the pandemic.

13. Recruitment during the pandemic proved significantly more challenging than anticipated. While prior studies by the team had achieved response rates near 80% with community center participants, this study's rate dropped to 50%, reflecting the broader public health crisis and its disproportionate impact on participating communities. These challenges were documented in two peer-reviewed publications. Due to pandemic-related delays, the NIH approved a no-cost extension for a fifth project year, permitting the use of unspent funds but not providing additional resources. At the time of termination, the team was actively analyzing data related to one of the study's primary outcomes—psychological distress—with plans to submit a manuscript in the spring. Analyses of the remaining primary outcomes related to sleep disorders were scheduled for the summer, with a goal of submitting a second manuscript by early fall. Final data management and sharing tasks, including the development of a study website, were planned for completion in the fall.

14. The project was fully aligned with the historic mission of NIMHD, which prioritizes research on minority health, health disparities, and the social determinants of health and aims to improve health outcomes for underserved and marginalized communities. Focused on the impact of discrimination on psychological distress, the study directly supported NIMHD's strategic goals and was met with strong enthusiasm from the program officer overseeing the grant. It also advanced NIH-wide priorities around health disparities, particularly aligning with key objectives of the two NIH-Wide Strategic Plans encompassing the study's project period, respectively for Fiscal Year 2016-2020 and Fiscal Year 2021-2025. True and correct copies of both NIH-Wide Strategic place are attached as Exhibit B and C, respectively. Both of these NIH-Wide Strategic Plans discussed the need to understand and reduce health disparities, with the FY 2021-2025 strategic plan in direct support of the purpose of the study that was terminated, stating, "NIH understands that health research needs to routinely incorporate constructs and measurement of structural racism or discrimination across multiple domains and levels of influence if minority health is to be optimized, health equity achieved, and health disparities eliminated." Ex. B, at 33. The project's contributions were recognized through an invitation to present findings at a 2024 NIH-sponsored public workshop on discrimination and health, underscoring its relevance, scientific value, and alignment with national research priorities.

15. On February 28, 2025, my institution received notice from NIH that the final year of the grant—amounting to $650,000—would not be funded because it "no longer effectuates agency priorities." A true and correct copy of this termination notice is attached as Exhibit D.

16. The notice gave no individualized reason why the grant was terminated but merely cited Termination Section 3 (DEI)—"[r]esearch programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry. . . and ultimately do not enhance health, lengthen life, or reduce illness," and "[w]orse, so-called diversity, equity and inclusion ("DEI") studies are often used to support unlawful discrimination . . . which harms the health of Americans."

17. Subsequently, on March 3 and March 7, I was sent a first and second revision notice of award. The first stated that no expenses could be charged to the grant going forward. That notice also disclaimed that the termination of the grant was being carried out under any of the president's executive orders. The second included this language and also stated that "with prior approval, a portion of funds may be used to support patient safety and orderly closeout of the project." A true and correct copy of these revised Notices of Award are attached as Exhibit E and F, respectively.

18. I don't understand what the termination notice means by "DEI" in relation to my scientific research study, which is concerned with testing hypotheses about the impact of multiple types of discrimination on health and had no aims regarding who would be employed on the project, nor do I understand how my project is "based on" "DEI." I also do not understand how my project, focused on the harmful effects of discrimination, could in any way be "used to support unlawful discrimination." I received no communication following up with clarification.

19. While the project investigates the broad impacts of discrimination on health outcomes, no individuals have been selected for or excluded from participation based on race, ethnicity, religion, gender, or sexuality. Participants are randomly selected patients from three community health centers who meet the following criteria: U.S.-born, working-age adults (25–64), able to complete an English-language survey, and mentally competent to provide informed consent. The study is not designed to focus on any specific group or protected characteristic; rather, its goal is to examine and quantify the effects of discrimination, which can impact individuals from any background.

20. To the best of my knowledge, it is highly unusual for a grant to be terminated or not renewed midway through a project, particularly after several years of progress. My understanding is that such an action would only occur in cases involving research misconduct or risks to

participant safety. In my decades-long career, I have never personally experienced a grant being discontinued in the middle of a project—until now.

21. The termination has had serious professional and material consequences. Scientifically, it halted progress on completing two of the study's primary aims, preventing us from completing planned analyses and sharing the knowledge generated with the broader scientific community and the community health center members. Logistically, it halted our ability to develop the infrastructure necessary to ethically share our data, via a public website, which is a necessary step to enable the conduct of rigorous reproducible science and also the efficient use of NIH-funded data by other investigators. The inability to complete our work as specified in our study timeline means that the scientific community loses access to valuable data and methods designed to advance understanding of how discrimination affects health outcomes, compromising both rigor and impact.

22. Several members of my research team—dedicated individuals who had committed years to this work—lost job security or experienced significant salary reductions. A full-time research coordinator position we had planned had to be scaled back, limiting our ability to attract and retain qualified candidates. These staffing losses, combined with the abrupt withdrawal of funding, have made it exceedingly difficult to complete the project's central aims or return the results to the community members and study participants who generously contributed their time and trust. Also affected by termination of the federal grant are the institutional staff members whose work is supported by the total grant funds and is vital to the successful conduct of the scientific research, including staff involved in grant administration, IT, data security, and human subjects compliance.

23. Finally, the suppression of critical research into the health impacts of discrimination has broader societal consequences. By halting work that could generate new methodologies and insights into how multiple types of discrimination, singly and combined, harms the health of individuals, the decision effectively curtails scientific inquiry into one of today's most pressing public health issues.

24. Because I no longer have federal funds to complete the study's stated objectives or deliver results to participating community health centers or study participants, I have spent countless hours trying to manage the fallout—supporting displaced team members, reassessing unfinished research, navigating complex administrative issues, and seeking other funding to complete the work. This has taken a considerable toll on my ability to focus on my other responsibilities,

including teaching, mentoring, and institutional service, as well as on my ability to focus on my other funded research projects and publication preparations. Beyond the immediate disruption, the termination has shaken the continuity of my research program and dampened morale among colleagues who fear similar outcomes for their own work. The experience has been both professionally destabilizing and personally demoralizing.

25. I appealed the termination on March 26, 2025.

26. Although I appealed the termination, I remain uncertain about how to respond to NIH's assessment that my project "no longer aligns with agency priorities," especially since I do not fully understand how my research is considered "based on DEI."

27. Additionally, I am unsure whether my appeal stands any chance of success, given the termination notice's statement that "[t]he premise of this award is incompatible with agency priorities, and no modification of the project could align it with agency priorities." Ex. D at 1.

28. I am also concerned that another grant application I have submitted, focusing on the continued impacts of Jim Crow on contemporary health inequities, will not be fairly considered or considered at all under NIH's changed priorities. In November 2024, the Scientific Review Group ranked the proposal in the top 10 percent during peer review. However, the February 2025 NIH NIMHD Advisory Council meeting—where the grant was to be discussed and potentially approved for funding—was canceled and has not been rescheduled. There is concern that the revised and highly rated proposal may remain in limbo due to the disruption in the review process and the nature of its subject matter.

29. I am submitting this declaration under seal due to serious concerns for my personal safety and privacy.

30. Colleagues of mine who have been publicly named in similar contexts have experienced harassment and doxxing. In the current political climate, the fact that my work addresses racism, gender inequality, LGBTQ health issues and societal determinants of health has heightened my concern that defending my work in a lawsuit may make me a target of such harassment.

31. Recently, following a February 2025 national media interview in which I discussed the ways in which key public health data and websites maintained by US health agencies were newly being suppressed due to their focus on health equity, environmental justice, climate change, and LGBTQ health, I received vaguely threatening mailed letter from a stranger, and I called my university's police department to have them open the letter and assess the level of threat involved.

This incident has heightened my fears of being personally targeted. While I welcome academic and public discourse about public health and equity, I do not wish for that engagement to compromise my personal safety.

32. I am also concerned about potential retaliation from the U.S. government. It is unclear why my grant was the first—and for a time, the only—scientific study (R01 grant) terminated under the "DEI" category, especially given the existence of many other federal research grants addressing discrimination and health. The timing of my termination, which occurred immediately after the NIH received authorization on the afternoon of February 28 to begin issuing such terminations, further compounds my concern.

I declare under penalty of perjury that the foregoing is true and correct.
Executed this 23rd day of April, 2025.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)

DECLARATION OF APHA MEMBER 2

I, [redacted], pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. My name is [redacted] and I serve as the Managing Director for [redacted] a small company dedicated to providing world-class education focused on pain research and neuroscience. In this position, I develop and coordinate educational modules, including webinars, conferences, and lectures for the continuing education of clinicians and researchers. I have held this position since I began working for [redacted] at the beginning of 2016.

2. I am offering this Declaration in my individual capacity and not on behalf of my employer.

3. I have 20 years of experience working on accreditation systems and instructional design, and I have been working in pain and neuroscience for the last decade. I began my career in this field at [redacted], where I served as the [redacted], and then worked at [redacted] as the [redacted]. I have also served as a [redacted] for the [redacted] for the last five years. My professional goal is to help other people do their jobs better.

4. Helping people who experience chronic pain is something I'm passionate about because it is one of the largest public health crises that is rarely discussed. Nearly 25% of American adults experience chronic pain and over 8% of American adults have chronic pain that frequently

limits their life or work. Children are also vulnerable to the impacts of chronic pain; they experience it at similar rates and it critically impacts their development and their lifelong relationship to healthcare. The economic burden of pain in the United States is more than the annual costs (in 2010 dollars) of heart disease ($309 billion), cancer ($243 billion), and diabetes ($188 billion) and nearly 30% higher than the combined cost of cancer and diabetes. Adjusted for inflation, chronic pain costs the United States nearly $1 trillion annually. I am also passionate about solving the problem of chronic pain because of its close relationship to the devastating effects of the opioid crisis. Almost one in four American adults know someone struggling with an opioid addiction. These are issues that affect almost all of us, and they deserve close attention.

5. I am a member of APHA and pay $230 in annual dues.

6. I am the Program Director for an R24 grant awarded by the National Institute of Health ("NIH"). R24 grants are issued by NIH to provide tools and resources in support of ongoing research. The grant award number is [redacted].

7. The grant funds the development and operation of a Coordinating Center for National Pain Scientists ("Coordinating Center"). As described in the Notice of Funding Opportunity ("NOFO") [redacted], the Coordinating Center is designed to be "a central facilitator for integrating training and mentoring across a network of mentors and early-stage investigators funded by the NIH," including NIH trainees, fellows, and others. The purpose of the Coordinating Center is to "enhance the training experience of new pain researchers across the continuum of basic, translational, and clinical research and create a vast network of NIH-funded pain researchers to promote multidisciplinary collaborations in pain research." A true and correct copy of [redacted] is attached hereto as Exhibit A.

8. The creation of the Coordinating Center is in direct response to the NIH Helping to End Addiction Long Term ("HEAL") Initiative®'s goal of building the pain workforce because there are not enough pain researchers to enhance and develop evidence-based approaches for pain management. The NIH has described this as an "urgent need" and has identified several factors that have contributed to a leaky workforce pipeline to pain research, including: challenging research environments for clinicians, a high departure rate from the field among senior researchers who serve as mentors for more junior researchers, a lack of structure for early-stage investigators to learn from experienced investigators, and a lack of collaboration between pain management researchers across disciplines. Furthermore, the Coordinating Center fills a gap in

NIH's structure because there is no NIH Institute for Pain that would normally serve as the coordinating and centralization entity for pain-related research and resources.

9. The Coordinating Center also responds to the priorities of other NIH Institutes and Centers ("ICs"). There are currently 27 ongoing clinical pain studies within the HEAL Initiative and there are thousands of more pain-related research programs across the ICs. This has led to a disjointed and uncoordinated approach which is a hinderance to the effective, multidisciplinary, and collaborative research that is needed to address such a grave public health problem. The Coordinating Center serves the function of connecting these researchers, educating them about the developing science of each other's studies, and helping to accelerate innovate approaches to pain management and treatment.

10. The Coordinating Center is also aligned with President Trump's Make America Healthy Again Executive Order and Commission which is tasked with addressing the key health priority of chronic disease. As described above, chronic pain is a largely silent public health crisis.

11. Applicants to this NOFO and all training-related grants were required to include elements from the Notice of NIH's Interest in Diversity NOT-OD-20-031. Specifically, the NOFO said,

> In addition to scientific diversity, applicants should strive to incorporate diversity in their team development plan. Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust. Please refer to Notice of NIH's Interest in Diversity NOT-OD-20-031 for more details.

A true and correct copy of NOT-OD-20-031 is attached hereto as Exhibit B.

12. Because of this requirement, the grant application for the Coordinating Center that I prepared described how the Coordinating Center would be open and available to all pain researchers, including those from underrepresented backgrounds, such as women, Black, and Latinx researchers, as well as researchers with a low socioeconomic status and researchers with disabilities. The goal of the Coordinating Center is to improve mentorship and collaboration among pain researchers and clinicians, so it is critical that *all* researchers feel welcome. However, explicit mention of underrepresented groups in the grant application was only included

because it was an NIH requirement at the time, and the proposed budget did not dedicate any financial resources to this ancillary aim of diversifying the workforce. The operation of the Coordinating Center complies with federal, state, and local laws. We have never performed any preferential hiring, nor have we distributed any travel scholarships based upon demographic categories.

13. Putting together the grant application for the Coordinating Center was extremely time intensive. During the final weeks, I worked 196 hours over 11 days. I stopped going into the office, slept some nights but not all, and at times forgot to eat for many hours. I met with software platform vendors and other vendors so I could pull together a budget justification that was accurate to the dollar. Because instructional design methodology is my specialty, I dedicated roughly half the application to describing the innovative approaches I developed to meet the needs of NIH. I also spent hours meeting with NIH program officers during the application process so I could fully understand NIH needs, including the scale of the Coordinating Center. During the competitive review process, NIH followed up with me for additional information, and the responses to those requests were also time intensive.

14. In September of 2022, NIH issued a Notice of Award ("NOA") for $6,882,205 for a period of three years (to end August 31, 2025) to fund the Coordinating Center. It was communicated to me that I would be able to apply for a Type 4 Non-Compete Renewal at the close of the grant to continue funding the Coordinating Center for at least another two years. A true and correct copy of that NOA is attached hereto as Exhibit C.

15. Since its launch, the Coordinating Center has been a massive success. It is the first and only mechanism for consolidating the entirety of pain researchers across the spectrum of basic, clinical, and translational research, at all career stages. This is primarily accomplished through an online hub that—among other things—indexes research studies, provides up-to-date contact information to enhance collaboration opportunities, connects researchers with clinical doctors who may have ready study participants, and aggregates funding and job opportunities. For example, a user of the hub who is interested in understanding pain associated with fibromyalgia can type the term into the network and instantly be connected with all the researchers who are doing this work. The Coordinating Center acts as a digital resource center and provides tools and support for other NIH-funded pain research programs, consolidating their resources into one

location while reducing the need for redundant, more costly infrastructure at each study site. To date, the online platform has nearly 5,000 users and the number is growing daily.

16. Another major way the Coordinating Center achieves its goals is through an annual conference that gathers pain researchers together to accelerate "bench to bedside" treatment, which is the process of translating scientific discoveries made by researchers into practical applications and improved patient care. At the conference, researchers have the opportunity to hear directly from people who have the conditions they aim to treat, which helps them develop new hypotheses or narrow in on hypotheses worth further testing. This annual meeting also serves as a required in-person investigator meeting for pain research programs funded under the HEAL Initiative and through individual ICs. It is the only place for many of these investigators and their research teams to meet in-person, collaborate, and connect with other NIH-funded pain researchers. By centralizing the in-person meetings for various studies and programs, the Coordinating Center has helped to reduce redundancy for multiple meetings, centralize planning resources, and approach pain research efforts as a holistic group instead of the status quo of individual meetings for each study. This has reduced overall costs for affiliated meetings, while enhancing efficacy. Overwhelmingly, participants say that they were "able to network with researchers from across the continuum of basic, translational, and clinical research," and that they now "plan to collaborate with at least one other researcher from a discipline different than their own."

17. To make the Coordinating Center as successful as it's been, I've had to hire three dedicated staff people: a Conference and Community Coordinator, a Community Engagement Coordinator, and a Digital Media Specialist. One hundred percent of their time is allocated to the Coordinating Center. I also spend approximately 55% of my time on the Coordinating Center.

18. And, in 2024 NIH issued a NOA to [redacted] for a Supplemental Award to support the HEAL PAIN Researcher Cohort Program ("PAIN Cohort Program"), an interdisciplinary training program among postdoctoral researchers pursuing careers in pain and addiction science. The Supplemental Award was a 5-year grant that required an annual Non-Compete Renewal. The first-year award was for $850,595, and because it is a Supplemental Award, the budget and project period end dates are the same as the parent award, described in paragraph 14 above. The Supplemental Award number is [redacted]. A true and correct copy of the NOA reflecting the Supplemental Award is attached hereto as Exhibit D.

19. The PAIN Cohort Program utilized the Coordinating Center to help foster collaboration and a shared learning experience across six universities: the University of Utah, Mass General Brigham, Stanford University, University of Michigan, University of Florida, and Washington University in St. Louis. Each university, in turn, recruited four trainees under the Ruth L. Kirschstein National Research Service Awards ("NRSA") program (T90 awards) and one trainee under the R90 grant program to bring postdoctoral researchers from various disciplines together to learn from one another. For example, one postdoctoral trainee might be from the school of dentistry and another from the school of engineering and through the program, they have the opportunity to develop innovative treatments and translate research findings into clinical practice.

20. The PAIN Cohort Program emphasizes mentorship, career development, and hands-on research experience, and the Coordinating Center is a critical tool for achieving those goals. The Coordinating Center provides the necessary infrastructure for trainees to coordinate with one another across institutions. Through the Coordinating Center, trainees can do their own research planning and develop materials to support that research. To support this collaborative effort, I redesigned a training curriculum so that it could work on a national scale and so trainees could learn in a timely and effective manner, including a weekly webinar series on pain research and soft skills. An added benefit of using the Coordinating Center as the central hub for the PAIN Cohort Program is that the materials and resources developed through the PAIN Cohort Program are also available to the larger Coordinating Center network. Additionally, the Coordinating Center establishes an enduring archive of this critical work.

21. I spend about 30% of my time working on the PAIN Cohort Program, meaning that 85% of my time is spent working on these two NIH-funded projects.

22. Given the success of the Coordinating Center, there has never been any indication that the Non-Compete Renewal I was set to apply for this year would not be granted. In fact, just last year I was awarded the NIH [redacted] Award for the work I've done on the Coordinating Center.

23. However, on March 21, 2025, before that renewal application was due, I received a termination letter from the NIH notifying me that my award was terminated. The letter said:

> This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives are antithetical to the scientific inquiry, do nothing to expand our

> knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore it is the policy of NIH not to prioritize such research programs.

A true and correct copy of the termination letter is attached hereto as Exhibit E.

24. The reasons given in the termination letter are inconsistent with the work of the Coordinating Center. The Coordinating Center does not spend any money on diversifying the biomedical research field. The Coordinating Center aims to enhance the field for all pain researchers, regardless of their race, gender, sexual orientation, or any other identity that might be understood to fall into that classification.

25. The termination letter also did not define the terms within it. Because the terms do not describe the work that the Coordinating Center does, it is unclear to me what criteria NIH used to determine that the Coordinating Center "no longer effectuates agency priorities."

26. When I reached out to my Program Officer to get clarity about why the funding had been terminated, I was informed that the IC had not been consulted about the termination of the grant and my Program Officer had also not been informed.

27. The next weekday after receiving the termination letter, on March 24, 2025, I appealed pursuant to the instructions in the termination letter. In drafting the appeal, I was left to guess how NIH applied the terms used in the letter to the Coordinating Center. I received an acknowledgment of receipt of the appeal, two weeks later, on April 7, 2025.

28. After submitting my appeal, I received a revised NOA with a revised project period end date of March 21, 2025. The revised NOA stated that the award is "related to DEI" and "no longer effectuates agency priorities" and was terminated for those reasons. A true and correct copy of the revised NOA is attached hereto at Exhibit F.

29. Because the Supplemental Award is connected to the Coordinating Center award, it has also been terminated. I received a revised NOA with a new project period end date of March 21, 2025. My Supplemental Award Program Officer told me that they had not been informed about the termination of my Supplemental Award. A true and correct copy of the revised Supplemental NOA is attached hereto at Exhibit G.

30. The impact of this termination is severe and dire. In a conversation with my grants manager at NIH, I was told that NIH would not cover unliquidated obligations that have already

been made in reliance on this funding. I have asked for this policy in writing, but have not yet received it.

31. If this is true, I may be faced with up to $1 million to pay for obligations already committed for the upcoming annual conference currently scheduled for June. For example, for almost two years, we've had a nearly $500,000 contract with the hotel that is set to host the conference. We also have a $120,000 planned expense for audio/video services for the conference. Additional food and beverage costs are also potentially on the line. If [redacted] is forced to pay these costs out-of-pocket, it would bankrupt the business.

32. Conference travel support was also funded through the grant. To date, approximately 100 people have applied for this travel support, and I must now determine who has been approved for that support and contact them to find out if they've purchased tickets that they now may not be reimbursed for. This poses a particularly upsetting challenge, since those attendees applied for travel support because they are unable to afford the costs on their own. Relatedly, many other grant programs throughout the NIH include requirements that their researchers attend the conference. If the conference is cancelled because of the termination, all the researchers who have already purchased plane tickets or made other travel arrangements have now wasted those federal funds. Likewise, it is unclear to me what will happen regarding faculty member reimbursements.

33. Even if NIH provides funding to cover these obligated costs, the conference cannot move forward, and all these expenditures will be wasted.

34. Additionally, the day that I received the termination letter, I had to furlough the three staff people who work with me on the Coordinating Center because 100% of their time was spent supporting this program.

35. I also am no longer receiving a salary, despite the time and costs associated with closing out the grant and resolving the financial burden caused by NIH's abrupt grant termination.

36. [redacted] does not have a fallback plan. As the Coordinating Center work scaled up over the years, our other educational programs have necessarily had to scale back. Other budget lines that kept us afloat in the past are no longer there.

37. Perhaps most concerning is the impact the virtually overnight disappearance of the Coordinating Center will have on the prospect of responding to the public health crisis of chronic pain and addiction. Without the Coordinating Center, researchers will go back to being siloed,

critical studies will struggle to find collaborators, promising developments in the field will not be shared broadly, and the scientists tasked with finding a solution to this critical problem will no longer hear from people with chronic pain in such an effective manner.

38. I am seeking to file this declaration under seal because I am scared for my own security, especially that I will get doxed. The current climate is particularly hostile and even though I believe NIH still intends to do good work, my association with this case could make it seem like I am oppositional to NIH's interests or biomedical research in general, when that is not the case. I am also worried that involvement in this case may jeopardize future NIH funding opportunities. Finally, I am also worried that my involvement in this case could have longer term negative consequences on my career because broad knowledge that my funding was terminated by NIH may suggest that I was not good at developing and providing continuing education, when that too is not the case.

I declare under penalty of perjury that the foregoing is true and correct.
Executed this 23 day of April, 2025.

[redacted]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF APHA MEMBER 4

I, Sereno "Sari" Reisner, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. My name is Sari Reisner and I am an adjunct associate professor with tenure in the Department of Epidemiology at the University of Michigan School of Public Health, as well as an adjunct associate professor in the Department of Epidemiology at Harvard T.H. Chan School of Public Health. I am a transgender population health researcher and have been working in this field since 2009, with a focus on infectious diseases and mental health. My research aims to address health inequities among underserved communities, particularly in relation to mental health, substance use, HIV, and access to high-quality healthcare.

2. I am offering this declaration in my individual capacity and not on behalf of my employer.

3. I received my Doctor of Science from the Harvard T.H. Chan School of Public Health in 2013 and completed two years of post-doctoral training in infectious disease epidemiology in the Department of Epidemiology at the same institution. I have led a range of community-engaged research projects, and am a longtime collaborator with Fenway Health, an LGBT healthcare, research, and advocacy organization, where I have overseen major grants with a team made up largely of transgender research staff.

4. Disenfranchised communities continue to face systemic barriers that lead to persistent health disparities, limiting their ability to thrive. My work is motivated by a desire to understand and help address these challenges. I focus on improving health and wellbeing in underserved populations, with the goal of supporting more effective and inclusive health systems that provide *everyone* with the opportunity to achieve their best possible health.

5. This work addresses a critical gap in public health research. HIV continues to be a major societal and economic burden, and transgender people and men who have sex with men are among the most affected. By focusing research on these communities, my work not only improves individual and community health outcomes but also advances the national public health goals laid out in the National HIV Strategy for the United States 2022-2025. That Strategy was published in 2021 by the White House as part of the Ending the HIV Epidemic in the U.S. (EHE) initiative launched by President Trump in 2019. A true and correct copy of this report is attached hereto as Exhibit A.

6. I have received NIH funding for my research for more than a decade, and I have applied for and received over a dozen grants from the NIH over the course of my career.

7. Each application has involved months—sometimes years—of work, from conducting background research and refining the study design to collaborating with colleagues across disciplines and gathering community input. The grant review process is highly rigorous, and securing funding has become increasingly competitive over time, with many successful proposals scoring in the top tenth percentile or better. One of my current projects, for example, was ranked in the first percentile, reflecting its strength and scientific rigor. Despite the challenges and competitiveness, I value this process for helping to ensure that the most rigorous and impactful research is conducted to advance the scientific evidence-base to improve health outcomes.

8. I am a member of the American Public Health Association (APHA) and pay $245 in annual dues.

9. The NIH has terminated five grants that supported my research, including four R01 grants and one U01 grant. I was the Principal Investigator for four of the projects these grants supported.

10. Among these terminated grants was an R01 grant (5R01MH129175) of approximately $4 million awarded by the National Institute of Mental Health (NIM) on August 19, 2022, titled *Strategies to Prevent HIV Acquisition Among Transgender MSM in the US.* A true and correct copy of my NOA is attached hereto as Exhibit B.

11. Transgender men who have sex with men (MSM) are a critical population for this work, as they have an 11-fold higher risk of HIV transmission than transgender men who do not have sex with men. The project was a randomized controlled trial with 375 participants using peer intervention to encourage the use of pre-exposure prophylaxis (PrEP) in order to address these higher rates of HIV in transgender MSM. There are no evidence-based interventions to address HIV risk in this population, and the study aimed to fill that gap. The study focused on the 57 U.S. jurisdictions with the highest rates of new HIV cases, as identified and prioritized by the White House Office of National AIDS Policy. Ex. A at 16. Reducing infections in these areas not only helps this specific population, but it also has the potential to significantly reduce the burden of care nationwide.

12. This study also utilized peer-delivered digital interventions, a model that could be adapted and applied to a wide range of populations and thereby open new avenues for future research and public health efforts. It used a digital randomized trial to test two peer-delivered HIV prevention strategies—one-on-one peer navigation and a small group program—either on their own or combined. The 375 participants, all HIV-negative trans MSM eligible for PrEP, were randomly assigned to one of four groups (each receiving different peer-delivered HIV prevention strategies designed to increase PrEP uptake) and studied over 21 months. Every three months, participants completed surveys, did at-home HIV testing, and submitted samples to measure PrEP use. The study also included interviews to better understand how participants make decisions about PrEP and what their experiences were like in the program. The goal of the project was to evaluate the effectiveness of digitally delivered, peer-based HIV prevention strategies in increasing PrEP uptake. By engaging transgender MSM as active partners in the research process, the project aimed to develop culturally tailored, community-informed approaches to HIV prevention. Ultimately, the study seeks to fill critical gaps in HIV prevention for this underserved population, with implications for other at-risk population, and contribute to national efforts to end the HIV epidemic.

13. In filling that critical gap, the research directly contributes to reducing infectious disease disparities and promoting health equity. It also fills a critical gap in biomedical HIV prevention research, an area long prioritized by NIH due to the disproportionate burden of HIV among marginalized communities. The study also supports NIH's commitment to community-engaged research and inclusive public health innovation, and advances national efforts outlined in the

2021–2025 U.S. National Strategic Plan to End the HIV Epidemic, reinforcing NIH's broader public health mission. Ex. A.

14. The application for this grant was the culmination of over a decade of research, beginning with a formative study in 2009 and followed by multiple qualitative, quantitative, and intervention studies that informed the final design. Developing the application took nearly a year and involved close collaboration with a team of six co-investigators from different institutions. The process was intensive, with significant time devoted to refining the proposal—including 50 to 60 hours in the final week alone. The application underwent two rounds of rigorous NIH peer review; while the first submission scored well, it was not initially funded. After careful revision and resubmission, it ultimately received a highly competitive score (scoring in the first percentile), reflecting both the quality of the science and the depth of preparation behind it.

15. By year three of the five-year project, we had hired a team of six staff members and four consultants, and were actively running a randomized controlled trial with 96 participants receiving intervention. Intervention was delivered by peers whom our team had trained, and was built on two years of collaboration with a national community advisory board to ensure materials were implementation-ready. Preparing for launch involved extensive groundwork, including over six months of staff training in facilitation, motivational interviewing, and crisis response, and work on branding and development of recruitment advertisements with a community artist. The project also included HIV testing, PrEP adherence monitoring through remote biospecimen collection, and coordination with an external laboratory. We had established a comprehensive study protocol, safety procedures, IRB approvals, and data management systems, and were six months into the 15-month observation period.

16. On March 21, 2025, NIH issued a termination notice, which stated that the award for this grant "no longer effectuates agency priorities." A true and correct copy of my termination notice is attached hereto as Exhibit C. Three days later, on March 24, 2025, NIH issued a revised notice of award (NOA) reflecting the termination of the grant and echoing the language included in the termination notice. A true and correct copy of the revised NOA is attached hereto as Exhibit D.

17. I was never given any previous indication that my grant was in jeopardy, including when NIH twice approved my annual renewal request.

18. Neither the revised NOA nor the termination notice includes any individualized explanation for why the grant was cancelled, and both fail to discuss any of the data or analysis

from our application, annual progress reports, or other related material. Instead, the termination notice includes the following language about its decision:

> This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Ex. C at 2; *see* also Ex. D at 5.

19. I don't understand what the termination notice means by "gender identity" in relation to my project, nor did I understand how my project was "based on" "gender identity." I received no communication following up with clarification. While the project did involve transgender participants, the research ultimately centered on examining sexual risk behaviors for HIV and biomedical prevention, which is based in biological and anatomical sex. The primary focus was on encouraging the use of PrEP, which is a biomedical intervention aimed at reducing HIV acquisition risk.

20. Our project targeted enrollment to include 50% people of color, with a geographic focus on areas experiencing the highest rates of new HIV diagnoses in alignment with the White House Office of National AIDS Policy's national strategy. Ex. A at 16. We also worked with transgender men who have sex with men, the group with the highest HIV risk. While we included diverse populations in our research, the study itself was not centered around gender identity but rather on addressing the biomedical aspects of preventing HIV acquisition.

21. My other grant terminations were communicated in nearly identical ways, with no individualized explanations as to why the awards were canceled. In total, four of my other grants were terminated with references to "gender identity," with identical (or nearly identical) language as the termination notice discussed above. One grant was terminated with reference to "DEI." Across all of these grant terminations, key terms like "gender identity" were never defined, and their relevance to the specific canceled projects were unclear.

22. Generally, grant projects are required to submit annual progress reports. It is my understanding that it is extremely rare for a grant to be terminated or not renewed mid-project, especially after several years of work. To my knowledge, the only reasons for such a drastic action

would typically involve research misconduct or harm to participants. In my multi-decade career, I had never personally encountered a grant being terminated in the middle of a project before now.

23. The impacts of the grant termination have been severe. I cannot pay my staff of six people and have lost three months of my own salary.

24. I will be restricted in my ability to work on a project that took years to develop and receive funding for. Further, the early termination of the program with active participants will certainly damage the trust I have built with this community.

25. At the time of termination, we were only about halfway through the 15-month intervention period for our participants. The data we have collected will now be unusable for analysis to achieve the project aims, and the biospecimen samples collected have been discarded.

26. At the time of termination, we were approximately halfway through the 15-month observation period with our study participants. The sudden halt means that the data collected to date—midpoint data from an incomplete intervention—cannot be meaningfully analyzed and will not support valid conclusions. Similarly, the biospecimen samples collected under the study protocol have been discarded, representing a permanent loss of both scientific and financial investment. Because of the tightly controlled experimental design, pausing the study mid-course breaks the protocol's integrity—making it difficult to resume the study in an acceptable way.

27. The termination of this grant additionally raises serious ethical concerns due to the lack of a clear process for participants actively involved in the trial. Without the ability to bill or invoice, and with no plan for study close-out activities, participants—who were receiving an intervention as part of the study—are left in an uncertain and unsupported position. As a highly marginalized and at-risk population with mistrust of healthcare and research settings, the abrupt termination of the project may not only cause immediate harm and distress, but may also have long-term consequences. Research has found that stigma in healthcare settings, including interruptions in continuity of care, results in future avoidance of healthcare; thus, the immediate termination may adversely impact this population's future engagement in healthcare and research settings.

28. Typically, a study termination involves a plan to safely transition participants off the intervention, notify Institutional Review Boards, and ensure no harm. The abruptness of this termination, without a mission plan or proper procedures in place, is highly unusual—such actions are generally reserved for cases involving participant harm or researcher misconduct.

29. About 80 former participants in the study reached out to share their gratitude for the researchers' work contributing to health efforts relating to transgender populations and express dismay at the news that the project would be terminated. I am concerned that these former participants, who entrusted us with their stories and experiences, will feel abandoned—and that the trust we built with a highly marginalized population may now be irreparably damaged. Many of them described the study as one of the few times they felt seen and valued in a healthcare or research setting. At the very least, this termination cuts short a vital opportunity to extend the insights and positive outcomes experienced by those participants to the broader transgender community.

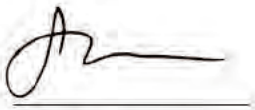
30. This grant supported predominantly transgender staff, meaning that the loss of this funding not only disrupts critical work but also undermines the capacity of a workforce that is both uniquely qualified and deeply connected to the populations they serve. The staff has also experienced severe emotional harm—many have expressed feelings of being devalued or targeted, and some are now questioning their place in public health entirely.

31. The termination of this portfolio of grants has left me uncertain about how to proceed, and it threatens my professional trajectory, ability to contribute to my field, and options for future career opportunities.

32. I worked with my university to file an appeal which was submitted April 18, 2025. Still, I do not know whether the appeal has any chance of success, given the termination notice's statement that modification of the project could align the project with agency priorities, and therefore no corrective action is possible. Ex. C at 2. I also did not know how to recharacterize my project in my appeal to fit within the asserted new agency priorities because I do not understand the terms used as the basis for termination.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 21st day of April, 2025.



Sari Reisner

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF APHA MEMBER 5

I, Jason "Jace" Flatt, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. My name is Jace Flatt and I am an Associate Professor in the Department of Social and Behavioral Health at the University of Nevada, Las Vegas, School of Public Health. I am a member of the International Research Grants Program Council of the Alzheimer's Association, the Healthy Brain Initiative Road Map Workgroup on Equity for the Centers for Disease Control and Prevention, the Alzheimer's Association, the Gerontological Society of America, and the American Public Health Association (APHA).

2. I am offering this Declaration in my individual capacity and not on behalf of my employer.

3. I've spent nearly 30 years focused on how we support individuals and families affected by Alzheimer's and related conditions. I received my master's degree in public health at the University of South Carolina, and went on to receive my PhD from the University of Pittsburgh's School of Public Health, where I also completed my postdoctoral fellowship in the Epidemiology of Aging & Population Neuroscience. While pursuing my PhD, a close family member was diagnosed with Alzheimer's, which further strengthened my dedication to this work.

4. My research focuses on understanding the experiences and health concerns related to Alzheimer's disease, Parkinson's disease, and other neurodegenerative conditions among LGBTQIA+ populations and their care partners. Prior to February 2025, I was Co-Principal Investigator of two National Institute on Aging-funded studies. The first was dedicated to recruiting and engaging LGBTQIA+ people with memory loss and their care partners into the RISE (Research Inclusion Supports Equity) Registry, and the second aimed to develop better ways of identifying and including LGBTQIA+ people who are taking care of someone with Alzheimer's disease so they're not left out of future research studies or support services. I study both risk and protective factors within these communities, as well as the needs of caregivers, healthcare providers, and those involved in long-term care.

5. I have received NIH funding for my research for more than a decade, and I have applied for and received nine grants from NIH for which I was Principal Investigator over the course of my career.

6. The application process for each grant was highly rigorous and time-intensive, often requiring months or even years of preparation. Writing a competitive application demands deep knowledge of the science, strategic team-building and experimental design, and careful alignment with NIH priorities through ongoing conversations with program officers. Once submitted, applications are reviewed by panels of field experts who assess the application's scientific significance, methodology, replicability, and overall rigor, typically with at least three in-depth reviewers per proposal. The process is extremely competitive—out of 40 to 50 reviewed proposals, only a few may be selected. The intensity of this process has historically served as a critical filter for supporting high-quality, meaningful research.

7. I am a member of the APHA and pay $210 in annual dues.

8. The NIH has terminated three grants that supported my research—grant numbers 5K01AG056669, 1R24AG066599, and 5R01AG083177.

9. Among these was an R01 grant (5R01AG083177) awarded by the National Institute on Aging on July 31, 2023, of approximately $3.5 million, titled *Enhancing Measurement and Characterization of Roles and Experiences of Sexual and Gender Minority Caregivers of Persons Living with Alzheimer's Disease and Related Dementias*. A true and correct copy of the NOA for this R01 grant is attached hereto as Exhibit A.

10. Nearly one million sexual and gender minority adults in the U.S. are caregivers, with nearly half of those providing care to someone with Alzheimer's disease or related dementia—yet, existing caregiving measures are outdated and fail to reflect the diversity of modern caregiving relationships. Against this backdrop, the project aimed to understand caregiving by sexual and gender minorities (SGM) for those with Alzheimer's disease in order to develop new or modified caregiving measures (such as survey tools, assessments of caregiver burden, or frameworks for evaluating support needs) and ensure that SGM caregivers are included in future caregiving research. The end goal of the project was to create six-eight new or refined measures that can improve support, services, and future research for both SGM and non-SGM caregivers.

11. This project used a mixed-methods approach, combining both qualitative and quantitative research to develop and validate more inclusive measures of caregiving for SGM individuals. In the first phase, focus groups and interviews with SGM caregivers would help identify key themes and experiences related to caregiving for those with Alzheimer's disease and related dementia. These insights would guide the creation and refinement of new caregiving measures, with input from experts and community partners through an online feedback process. The revised measures would be refined based on cognitive interviews with caregivers to ensure they are clear, relevant, and accurately reflect their experiences. The research team would pilot-test the refined measures through a survey of an independent sample of SGM and non-SGM caregivers to evaluate their clarity, reliability, and validity across diverse caregiving experiences.

12. I applied for the award in response to a Request for Applications (RFA) posted by the National Institute on Aging on June 09, 2022. A true and correct copy of a printout of the RFA webpage, accessed April 18, 2025, is attached hereto as Exhibit B. The RFA invited Research Project Grant (R01) applications for "the development of methods and measures for capturing expanded definitions of 'family' and related concepts relevant to informal caregiving for people living with Alzheimer's disease (AD) and Alzheimer's disease-related dementias (ADRD), and for the implementation of these measures in new and existing studies." Ex. B. The RFA specifically notes, "Existing measures also may fail to capture family structure differences for specific populations. For example, despite increased acceptance and legal recognition of sexual and gender minority (SGM) individuals and their relationships, little is known about how family care patterns vary by SGM status." *Id.*

13. I developed the application, including its focus on SGM populations, in explicit response to NIH's specific call for research. Generally, the project was aligned with longstanding NIH goals of advancing health equity, supporting inclusive research, and improving the rigor and relevance of health measurement tools. By developing validated caregiving measures that reflect the experiences of SGM populations, the study supports the broader efforts of NIH and the National Institute on Aging to improve care and outcomes for those affected by Alzheimer's disease and related dementias.

14. After learning about the RFA in July 2022—just three months before the application deadline of October 20, 2022—I began developing the proposal while juggling a full-time teaching load and other ongoing research. The process was brutal—I worked on the application whenever I had a second to spare, often during early mornings, late nights, and weekends. The final application was over 200 pages long. After several months of review, NIH responded in April 2023 with a set of critiques, which required a careful, point-by-point written response.

15. The project had made strong progress, driven by a team of six graduate students, two full-time staff, and three principal investigators across institutions, each leading their own research teams. We'd established two active community advisory boards: one of national dementia caregiving experts, and another of LGBTQIA+ senior community leaders. Each board included 10–12 members, all who would receive $1,000 annual honorariums, totaling about $24,000 per year over five years. These boards meet multiple times a year and contributed to the study by reviewing materials, supporting participant recruitment, and promoting the project at community events. At the time of termination, we were still in the final data collection phase before interviews, and were preparing to launch the next stage, focused on measure development, with support from the community advisory boards.

16. Just over a year into the five-year R01 grant, on March 24, 2025, NIH revised the NOA to terminate the grant, stating that the award "no longer effectuates agency priorities." A true and correct copy of the revised NOA is attached hereto as Exhibit C.

17. I had never received any previous indication that my grant was in jeopardy, and there had been no indication that I was not meeting the required milestones in my last progress report.

18. The revised NOA does not include any individualized explanation for why the grant was canceled, and fails to discuss any of the data or analysis from our application or related materials. Instead, the revised NOA includes the following language about NIH's decision:

> It is the policy of NIH not to prioritize Gender: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Therefore, this project is terminated.

Ex. C.

19. I don't understand what the revised NOA means by "gender identity" in relation to my project, or how it was "based on gender identity." I received no communication from NIH officials following up with clarification.

20. While the project did involve transgender participants, the research centered on guiding the creation and refinement of new caregiving measures to inform future aging and dementia research, and it was also focused on the development of these caregiving measures.

21. Even so, in October 2016, NIH, National Institute on Minority Health and Health Disparities (NIMHD), and the Agency for Healthcare Research and Quality (AHRQ) officially designated SGM as a health disparity population for research, indicating that research concerning this particular group was a priority for NIH. A true and correct copy of a printout of this NIH webpage, accessed April 18, 2025, is attached hereto as Exhibit D. I built expertise in this area of research concerning the SGM population because doing so was something NIH had indicated it wanted from researchers.

22. As a mid-career researcher familiar with NIH processes and norms, I know that early termination under these circumstances is highly unusual and inconsistent with established practice. It is extremely rare for a grant to be terminated or not renewed mid-project, especially after several years of work. To my knowledge, the only reasons for such a drastic action would typically involve misconduct or harm to participants. But I have never had any reported adverse events, concerns raised about the use of research funds, or issues related to scientific misconduct on this or any of my projects.

23. My other grant terminations were communicated in nearly identical ways, with no individualized explanations as to why the awards were canceled.

24. The impacts of the grant termination have been severe. In total, at least 35 people across teams will be losing their jobs or a portion of their income as a result of this grant termination.

This includes graduate students nearing the completion of their degrees, staff members, and collaborators across several institutions.

25. Administrative tasks related to the grant termination have overwhelmed my schedule, requiring countless hours of unpaid work to navigate meetings with staff, HR, and school leadership as I proceed with team layoffs.

26. The abrupt termination of these grants immediately stopped all work and billing conducted within the scope of the funded project. I am able to continue supporting two full-time staff and six graduate students for 30 days by using funding from a separate foundation grant. Previously, the work funded by this foundation grant had represented only a small portion of my team's time, but it now represents the majority of their workload. Not only has this shift been drastic and abrupt for my team, but it also will not be sustainable—the funding from this grant will dry up in a matter of months, and I do not anticipate being able to secure alternative funding to make up long-term for the salary of these team members.

27. I have lost my summer salary and will have to teach a higher course load to compensate, which will also make it harder for me to conduct research.

28. The grant termination means I can no longer take on new graduate students, undermining my ability to fulfill my role as a mentor and educator in training the next generation of scientists at my institution. I fear that, in the future, only those graduate students with the resources to self-fund or sustain themselves through their education and training will have the means to pursue research as a career, creating potential additional inequities in the field of public health and what projects are seen as most valuable.

29. The termination of the grant also led to the abrupt loss of ongoing engagement with the two community advisory boards composed of leaders in LGBTQIA+ aging and caregiving. These advisors brought invaluable lived experience and professional insight and participated in regular meetings, recruitment support, content review, and community outreach.

30. While progress on the project has ceased, the scale of these advisors' professional commitments means they must turn to other work and will likely be unavailable for future collaboration even if the project resumed. This represents a significant loss of community partnership, expertise, and trust, which will be difficult—if not impossible—to rebuild.

31. After spending nearly two decades building my career and securing an R01—one of the premier grants in my field—having NIH swiftly take it away is a significant personal and professional setback.

32. Beyond that, the participants in the study—all LGBTQIA+ caregivers for people with Alzheimer's disease—had each spent over a year answering questions about their caregiving experiences in an effort to develop measures that would be helpful for other caregivers in the future. Since we had to abruptly pause our data collection, we cannot draw conclusions and run analyses, and the anticipated research product focused on measurement development will not be completed.

33. Even if I were able to find funding to continue the work, I would almost certainly not be able to have the study's former participants work with me again—the LGBTQIA+ caregivers' trust with the researcher has been broken.

34. The loss of this R01 grant additionally undermines efforts to ensure that national data and public health interventions reflect the realities of today's caregiving landscape and account for non-traditional caregivers, such as chosen family members, non-married partners, or those providing care from a distance. As a result, individuals living with Alzheimer's disease or related dementias may be left without support systems that reflect their actual care networks, limiting the effectiveness of interventions designed to improve their quality of life and long-term outcomes.

35. I am appealing the terminations, but I do not know how to recharacterize my project in my appeal to fit within the asserted new agency priorities because I do not understand the terms used as the basis for termination. I also do not know whether the appeal has any chance of success, given the language of the termination notice states that the premise of my grant is incompatible with agency priorities.

36. I have no sense of whether my past work might be viewed as a liability when applying for future federal grants. This has led me to pause all current NIH grant applications while I await additional guidance, exacerbating my current funding issues.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 21st day of April, 2025.

Jace Flatt

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)"

DECLARATION OF APHA MEMBER 7

I, [redacted], pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. My name is [redacted] and I am a tenured Professor at a public university in the Northeast. I am a physician-scientist and specialize in research that focuses on [redacted] and I also practice medicine in this area.

2. I am offering this Declaration in my individual capacity and not on behalf of my employer.

3. I have been a doctor since 2005. I did my residency in [redacted], completed fellowships and remain board certified in [redacted] and [redacted] and am board certified in [redacted] My PhD is in [redacted] and [redacted] from a school of Public Health. I have published 150 peer-reviewed articles and six books, book chapters, and monographs throughout my career.

4. Most recently, my research has focused on [redacted] can lead people to [redacted] that temporarily [redacted]. However, these [redacted] don't work very well long term, and carry risks including [redacted]. people with [redacted] are

also more vulnerable to developing [redacted], [redacted], among other means. Additionally, [redacted] diagnoses like [redacted], and [redacted] are associated with [redacted] Therefore, [redacted] highly complex. Historically, the scientific [redacted] research and clinical medicine have been [redacted], but in practice if you don't [redacted], including how these [redacted], you are unlikely to [redacted]. I became passionate about these issues because I saw them so often clinically. [redacted] is so common in the United States that almost every American has experienced these challenges personally or in someone they love. I have dedicated my career to addressing the critical problem of treating [redacted].

5. I am a member of APHA and pay $230 in annual dues.

6. I am the Principal Investigator for a T32 grant awarded by the National Institute of Health ("NIH"). As described in NIH PA-20-142, T32 grants are Ruth L. Kirschstein National Research Service Awards (Kirschstein-NRSA) and are issued by NIH to enhance pre- and post-doctoral research training to ensure that a diverse pool of scientists are available in various scientific disciplines to address biomedical, behavioral, and clinical research needs. The grant award number is [redacted]. A true and correct copy of the expired PA-20-142 is attached hereto as Exhibit A.

7. The grant I was awarded funds a training program called [redacted]. This program provides personalized and rigorous training to postdoctoral fellows who plan careers at [redacted] Fellows are mentored on a longitudinal research project by experts in the field, participate in a rigorous, comprehensive curriculum based on core clinical and translational science competencies, attend annual retreats and in-person conferences, and participate in short-term research experiences. [redacted] was designed to have a [redacted] allowing the program to reduce barriers that would normally be presented by requiring fellows to [redacted] research hub. [redacted] prioritizes recruitment of fellows who will contribute to the diversification of the workforce.

8. [redacted] is aligned with the NIH [redacted] ("[redacted]") Initiative and leverages an NIH-funded network called the [redacted] network. This network is made up of [redacted] throughout the United States that focus on [redacted], and there is frequent collaboration between [redacted]. That said, [redacted] does not have a dedicated focus on workforce development, especially at the postdoctoral stage, and [redacted] addresses the critical need to develop a clinical research training program that directly addresses [redacted]

9. [redacted] further aligns with NIH's historical goal of building a diverse workforce. Indeed, PA-20-142 explicitly said T32 grants were meant to "help ensure that a diverse and highly trained workforce is available to meet the needs of the Nation's biomedical behavioral, and clinical research agenda." Id. at 2. It also said "[t]he overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines . . ." Id. at 3. Furthermore, it directly instructed applicants to give attention "to recruiting and retaining trainees from diverse backgrounds, including groups underrepresented in the biomedical, clinical, behavioral and social sciences, as described in the Notice of NIH's Interest in Diversity." Id. An applicant's recruitment plan to enhance diversity was even a review consideration: "Peer reviewers will separately evaluate the recruitment plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of prospective individuals from underrepresented groups. The plan will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the consensus of the review committee will be included in an administrative note in the summary statement." Id. at 11.

10. Accordingly, [redacted]s central aim of building a diverse workforce reflected NIH priorities but also a scientific need: [redacted]are complex problems involving biological, psychological, cultural factors that require creative solutions informed by diverse perspectives. Because of this, the grant application for [redacted] relied extensively on language included in the NIH definition of diversity and the CDC's Health Equity Guiding Principles for Inclusive Communities.

11. Putting together the grant application for [redacted] was extremely time intensive. It is not an exaggeration to say that I spent thousands of hours working on the application. In addition

to developing the program plan, several partnerships with scientists who would serve as mentors were needed to lay the foundation for a successful program. This involved hours of networking, outreach, and conversations to explain the purpose and design of [redacted]. The application also required letters of recommendations, which required identifying appropriate people, making the request, and tracking the status of the letters to ensure they were submitted on time. I spent about a 6-month period intensively writing the application, and in the end the application package was over 550 pages. Despite enthusiasm for key features of the proposal, the first application I submitted was not funded because the study section wanted further clarification on how [redacted] would occur and proffered constructive criticism on the program plan. Thankfully, I was given the opportunity to resubmit, and I was encouraged to do so by my NIH program officer. Reworking the application was an added lift, and I spent hundreds of hours revising for resubmission.

12. On June 14, 2024, NIH issued a Notice of Award ("NOA") for a five-year project period running [redacted] to [redacted] with a cumulative total award amount of [redacted]. Funding for this whole five-year period was contingent upon submission of annual non-competitive renewals to ensure program goals were being met. A true and correct copy of that NOA is attached hereto as Exhibit B.

13. I launched [redacted] immediately upon receiving the NOA and have been working on operationalizing the training program ever since. Most of the activities in our first year have been geared towards start-up. For example, we made a website, created an online application system for interested fellows, designed an evaluation process for reviewing applicants, and advertised among professional societies. Initially, we recruited two fellows, however one decided not to become a researcher because of concerns about the federal funding climate in the current administration. Since then, we've recruited two additional fellows who were to begin the [redacted] training program in July, bringing the total number of fellows to three. Despite the stated goal of diversifying the number of researchers studying [redacted], race was not a criteria for selection and of the four fellows recruited, all have been white.

14. The one fellow who is in their first year of the [redacted] program has had a fantastic start. The training they have received has been extensive and includes a three-day writing retreat, a conference where they had the opportunity to interact with several high-level NIH staff and

scientists from around the United States, and coursework. The training program is structured so that the fellows can participate in ongoing research projects, as well as launch their own new research projects with close mentorship. So far, the current [redacted] fellow has supported ongoing research [redacted] that is being conducted at my university, and they have just started thinking about their focused research project. They have had several brainstorming sessions with various mentors and are actively thinking about what direction they want to take their research scientifically. When the grant was terminated, they were in the process of writing their "Aims" page, which describes a project's rationale, objectives, hypotheses, and important elements of the research approach.

15. However, on March 21, 2025, I received a termination letter from the NIH notifying me that my award was terminated. The letter said:

> This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

A true and correct copy of the termination letter is attached hereto as Exhibit C.

16. On March 22, 2025, a revised NOA was posted online with a revised project period end date of March 21, 2025. The revised NOA said,

> It is the policy of NIH not to further prioritize research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry [sic], do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately to not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination since race and other protected characteristics, which harms the health of Americans [sic]. Therefore, this project is terminated.

A true and correct copy of the revised NOA is attached hereto as Exhibit D.

17. Nothing in the termination letter or the revised NOA was specific to [redacted] and I was not provided with an individualized explanation as to why the grant was cancelled.

18. Also, neither the termination letter nor the revised NOA defined the terms within it, and I don't understand what is meant by "DEI" in this context. On the face of my grant application, I

did talk about diversifying the workforce, but I am left to guess as to what aspect of diversifying the workforce does not fit NIH's new priorities. The [redacted] program does not preferentially admit people based on any demographic criteria. As mentioned before, all four fellows who have been selected happened to have been white; they were selected because they were the strongest candidates within the pool of applicants. Furthermore, some of the applicants who were not selected met the definition of diversity that NIH has historically used. They were not selected because they were either underqualified or their application materials did not demonstrate that their skillset was strong enough to be successful in the program.

19. The termination letter and the NOA also say [redacted] is "unscientific" which is untrue. The [redacted] program is grounded in research on curriculum design and several experts in fields such as [redacted] and clinical research were engaged in developing the program. [redacted] is pedagogically sound. Likewise, the research projects that fellows support and design as part of the mentorship aspect of the program are developed with key scientific principles at the forefront. The purpose of the program is to ensure early career researchers have the tools necessary to build strong careers in the biomedical field; it would be counterintuitive and counterproductive to train them to practice science in an "unscientific" manner. As such, it is unclear to me what "unscientific" means in the context of [redacted].

20. This termination is shocking because over the course of the 10 years I have been applying for NIH funding, I have been awarded seven grants. Before January 20, 2025, I have never had an NIH grant terminated, nor am I aware of any other NIH grants among colleagues that had been terminated. A grant termination was something I had never even given much thought to as a possibility.

21. The termination of the [redacted] grant has profound consequences. Most immediately, the one fellow that is in the middle of the program has had all their funding terminated. Beyond the financial hardship they are suddenly thrust into, in a field where NIH funding is critical to longer term career growth and finding institutions to support your research, this is devastating.

22. The personal consequences to this termination are also difficult to swallow. I have spent years designing this program, and bringing it to life was a career highlight for me. I also have no idea what the longer-term consequences will be to having had a grant terminated; I don't know if it will make future funding opportunities with NIH more difficult to compete for, or if being marked as having done something "unlawful" will be a scarlet letter I'm forced to carry.

23. And this termination will be devastating for the field [redacted] research. As far as I know, there were only two T32 training programs [redacted] in the United States, [redacted] being one of them. Now there is only one. The intention was to help create the next generation of scientists in this space and without [redacted] this mission is all but squandered. The impacts of this will be most heavily felt by the millions of people in this country and elsewhere who live with [redacted]. There will be a dearth of important innovations designed to improve the lives of people experiencing these horrible conditions. We cannot even know what lifechanging treatments will now go undiscovered without this funding.

24. I have appealed this decision, however I found it very difficult to write the appeal because I do not understand the terms used as the basis for the termination and I wasn't sure how to recharacterize [redacted] to fit within the asserted new agency priorities. Despite this difficulty, I appealed because I do not want it to stand that NIH said I was doing something illegal when nothing about [redacted] was against the law. I have no sense of whether the appeal will be successful.

25. I am seeking to file this declaration under seal because I am scared for my own safety. I am currently in the process of [redacted] and given the current political climate, I am worried that my involvement in this case may make me a target. I am also concerned that my involvement in this case may result in me getting blacklisted by NIH. In addition to future funding opportunities, I have other NIH grants that I fear might get cancelled for no other reason than my participation in this lawsuit. This could potentially put my entire career at risk. Additionally, I fear that my involvement in this case could put [redacted], at risk.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 22 day of April, 2025.

[redacted]

EXHIBIT A

This notice has expired. Check the NIH Guide (https://grants.nih.gov/funding/searchguide/) for active opportunities and notices.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Cancer Institute (NCI (http://www.nci.nih.gov/))
National Eye Institute (NEI (http://www.nei.nih.gov/))
National Human Genome Research Institute (NHGRI (http://www.genome.gov/))
National Heart, Lung, and Blood Institute (NHLBI (http://www.nhlbi.nih.gov/))
National Institute on Aging (NIA (http://www.nia.nih.gov/))
National Institute on Alcohol Abuse and Alcoholism (NIAAA (http://www.niaaa.nih.gov/))
National Institute of Allergy and Infectious Diseases (NIAID (http://www.niaid.nih.gov/))
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS (http://www.niams.nih.gov/))
National Institute of Biomedical Imaging and Bioengineering (NIBIB (http://www.nibib.nih.gov/))
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (http://www.nichd.nih.gov/))
National Institute on Deafness and Other Communication Disorders (NIDCD (http://www.nidcd.nih.gov/))
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (http://www.niddk.nih.gov/))
National Institute on Drug Abuse (NIDA (http://www.nida.nih.gov/))
National Institute of Environmental Health Sciences (NIEHS (http://www.niehs.nih.gov/))
National Institute of General Medical Sciences (NIGMS (http://www.nigms.nih.gov/))
National Institute of Mental Health (NIMH (http://www.nimh.nih.gov/))
National Institute of Nursing Research (NINR (http://www.ninr.nih.gov/))
National Center for Complementary and Integrative Health (NCCIH (http://www.nccam.nih.gov/))
Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP (http://dpcpsi.nih.gov/orip/index.aspx))

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the **Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/nrsa-institutional-research-training-grant-parent-t32.html)** website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

Funding Opportunity Title

Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32)

Activity Code

T32 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t32&Search.x=0&Search.y=0&Search_Type=Activity) Institutional National Research Service Award (NRSA)

Announcement Type

Reissue of PA-18-403 (https://grants.nih.gov/grants/guide/pa-files/pa-18-403.html) for due dates on or after May 25, 2020

Related Notices

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=32974) associated with this funding opportunity

- **January 26, 2023** - This PA has been reissued as PA-23-048 (//grants.nih.gov/grants/guide/pa-files/PA-23-048.html)
- NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available
- NOT-OD-22-190 (/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022
- **February 04, 2022** - Notice of Change in Interest Areas Relevant to the NIDDK for PA-20-142 Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32). See Notice NOT-DK-22-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-22-012.html).
- **December 7, 2021** - Notice of Additional Receipt Cycle for T32 Grant Applications. See Notice NOT-DA-21-088 (//grants.nih.gov/grants/guide/notice-files/NOT-DA-21-088.html)
- **October 28, 2021** - Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 - New Grant Application Instructions Now Available. See Notice NOT-OD-22-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-018.html).
- **September 13, 2021** - Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice NOT-OD-21-181 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-181.html).
- **August 5, 2021** - New NIH "FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice NOT-OD-21-169 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-169.html)
- **August 5, 2021** - Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice NOT-OD-21-170 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-170.html)
- **April 20, 2021** - Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice NOT-OD-21-109 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-109.html)
- **October 21, 2021** - Notice of High Priority Research Areas for NIDA T32 Training Grants. See Notice NOT-DA-21-087 (//grants.nih.gov/grants/guide/notice-files/NOT-DA-21-087.html)
- **May 11, 2020** - NIH Late Application Policy for Institutional Training Grants to PA-20-142 and PA-20-162 Due to Public Health Emergency for United States Coronavirus Disease 2019 (COVID-19). See Notice NOT-OD-20-105 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-20-105.html).
- **April 16, 2020** - Notice of Change in Interest Areas Relevant to the NIDDK Division of Kidney, Urologic and Hematologic Disorders for PA-20-142, Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32). See Notice NOT-DK-20-023 (/grants/guide/notice-files/NOT-DK-20-023.html).

Funding Opportunity Announcement (FOA) Number

A1134

REVIEWED

PA-20-142

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.398; 93.867; 93.172; 93.837; 93.840; 93.838; 93.839; 93.866; 93.273; 93.855; 93.846; 93.286; 93.865; 93.279; 93.173; 93.113; 93.859; 93.242; 93.361; 93.351; 93.213

Funding Opportunity Purpose

The National Institutes of Health (NIH) will award Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants (T32) to eligible, domestic institutions to enhance predoctoral and postdoctoral research training, including short-term research training, and help ensure that a diverse and highly trained workforce is available to meet the needs of the Nation's biomedical, behavioral, and clinical research agenda. Research training programs are expected to incorporate didactic, research, and career development elements to prepare trainees for careers that will have a significant impact on the health-related research needs of the Nation. Programs proposing only short-term predoctoral research training should not apply to this announcement, but rather to the Kirschstein-NRSA Short-Term Institutional Research Training Grant Program (T35) exclusively reserved for predoctoral, short-term research training.

This Funding Opportunity Announcement (FOA) does not allow appointed Trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Key Dates

Posted Date

March 20, 2020

Open Date (Earliest Submission Date)

April 25, 2020

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11111) apply

All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Standard AIDS dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11112) apply

All applications are due by 5:00 PM local time of applicant organization. All types of AIDS and AIDS-related applications allowed for this funding opportunity announcement are due on the listed date(s).

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Scientific Merit Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Advisory Council Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Earliest Start Date

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Expiration Date

May 8, 2023

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Training (T) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the

program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (NRSA) (//grants.nih.gov/grants/guide/url_redirect.htm?id=41125) website.

Purpose and Background Information

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Research training activities can be in basic biomedical or clinical sciences, in behavioral or social sciences, in health services research, or in any other discipline relevant to the NIH mission. Each program should provide high-quality research training, mentored research experiences, including training in appropriate methods, technologies, relevant quantitative/computational approaches, rigorous experimental design, and interpretation of data, and professional development skills such as communication, management, leadership, and teamwork.

Institutional NRSA programs allow the Training Program Director/Principal Investigator (Training PD/PI) to select the trainees and develop a program of coursework, mentored research experiences, and technical and professional skills development appropriate for the selected trainees.

The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels.

Program Objective

The objective of the Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (T32) program is to develop and/or enhance research training opportunities for individuals interested in careers in biomedical, behavioral and clinical research that are relevant to the NIH mission. As the scientific enterprise has expanded, there is greater variation in the backgrounds of people participating, approaches taken to investigate research questions, and the range of the careers in the biomedical research workforce that doctoral recipients are pursuing. There is also increasing recognition of the need to enhance reproducibility of biomedical research results through scientific rigor and transparency.

Proposed training programs are expected to help trainees develop the following:

- The skills to independently acquire the knowledge needed to advance their chosen field;
- The ability to think critically, independently, and to identify important research questions and approaches that push forward the boundaries of their areas of study;
- An understanding of the health-related sciences and the relationship of their research training to health and disease;
- A strong foundation in scientific reasoning, rigorous and reproducible research design, experimental methods, quantitative/computational approaches, and data analysis and interpretation;
- A commitment to approaching and conducting research responsibly and with integrity;
- Experience initiating and conducting research, and interpreting research findings with increasing self-direction, as well as presenting and publishing their research findings;
- Opportunities to interact with members of the broader scientific community at appropriate scientific meetings and workshops;
- The ability to work effectively with colleagues from a variety of backgrounds and scientific disciplines to contribute to inclusive and supportive scientific research environments;
- The knowledge, professional skills, and experiences required to identify and transition into careers that sustain biomedical research in areas that are relevant to the NIH mission.

The proposed institutional research training program may complement other ongoing research training and career development programs at the applicant institution, but must be clearly distinct from related programs currently receiving Federal support.

Program Considerations

The duration of training, the transition of trainees to individual support mechanisms, and their transition to the next career stage are important considerations in institutional training programs. Training PDs/PIs should limit appointments to individuals who are committed to a research career and who plan to remain in training for no less than two years, whether that support comes from a training grant or some combination of NRSA and non-NRSA programs. Training PDs/PIs should encourage and make available appropriate skills training so that trainees are prepared to apply for subsequent independent support for their training, career development or research program (e.g., an individual fellowship award, mentored career development award, or research project grant), as appropriate for their career stage. In addition, past studies have shown that health professional trainees who train in programs with postdoctoral researchers who have intensive research backgrounds are more likely to apply for and receive subsequent research grant support. Programs that emphasize research training for individuals with the MD or other health-professional degrees are therefore encouraged to develop interactions with basic science departments and include trainees with research doctorates when this approach is consistent with the goals of the proposed training program.

Biomedical research and the resulting scientific knowledge are increasingly complex and multidisciplinary in nature. Training PDs/PIs are encouraged to develop institutional training programs that will provide trainees with education and experience in a diversity of rigorous and reproducible scientific approaches, systems for study, tools and technologies. Consideration of team-based research approaches may also be warranted depending upon the goals of the proposed training program. Funded training programs must ensure that trainees have a solid foundation in methods to enhance data reproducibility through rigor and transparency.

Within the framework of the NRSA program's longstanding commitment to excellence, attention should be given to recruiting and retaining trainees from diverse backgrounds, including groups underrepresented in the biomedical, clinical, behavioral and social sciences, as described in the Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

Institutional commitment and support for the proposed training program are important elements of the application. The research training program may complement and synergize with other ongoing federally-supported research training programs at the applicant institution (e.g., in the development of skills needed for careers in the research workforce that are not discipline-specific).

The career outcomes of individuals supported by NRSA training programs include both research-intensive careers in academia and industry and research-related careers in various sectors, e.g., academic institutions, government agencies, for-profit businesses, and private foundations. Training programs should make available structured, career development advising and learning

opportunities (e.g., workshops, discussions, Individual Development Plans). Through such opportunities, trainees are expected to obtain a working knowledge of various potential career paths that would make strong use of the knowledge and skills gained during research training and the steps required to transition successfully to the next stage of their chosen career.

Institutional research training grants must be used to support a program of full-time research training. Within the full-time training period, research trainees who are also training as clinicians must devote their time to the proposed research training and confine clinical duties to those that are an integral part of the research training experience or can be conducted in the allowable additional 25% of their time (e.g., 10 hours per week) that may be devoted to clinical employment. The program may not be used to support studies leading to the MD, DDS, or other clinical, health-professional degrees except when those studies are part of a formal combined research degree program, such as the MD/PhD. Similarly, trainees may not accept NRSA support for clinical training that is part of residency training leading to clinical certification in a medical or dental specialty or subspecialty. It is permissible and encouraged, however, for clinicians to engage in NRSA-supported, full-time postdoctoral research training even when that experience is creditable toward certification by a clinical specialty or subspecialty board.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training. Short-term positions should be requested at the time of application, as described in the *NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11.1_general.htm)*. Research training programs solely for short-term research training should not apply to this announcement, but rather the T35 NRSA FOA, which can be found in the NIH Training Kiosk. (https://researchtraining.nih.gov/programs/training-grants)

This Funding Opportunity Announcement (FOA) does not allow appointed Trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this FOA, prospective applicants **MUST** consult the **Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/nrsa-institutional-research-training-grant-parent-t32.html)**, to make sure that their application is appropriate for the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Renewal
Resubmission
Revision

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials

Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited, but need to reflect the actual needs of the proposed project.

Grantees are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (*NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards for T32 institutional NRSA research training grants may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

Trainee travel to attend scientific meetings and workshops that the institution determines to be necessary for the individual's research training experience is an allowable trainee expense for predoctoral and postdoctoral trainees.

The amount of funds provided for trainee travel may vary by NIH Institute or Center; applicants are encouraged to consult the Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent-T32-institutional-research.html) for further information.

For short-term trainees, the NIH awarding component may provide grant funds to cover the costs of trainee travel, including attendance at scientific meetings, which the organization determines is necessary to the individual's training. Trainees must be appointed to the training grant at the time of the actual travel for this to be an allowable cost.

Training Related Expenses

NIH will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, equipment, research supplies, and faculty/staff travel directly related to the research training program. The most recent levels of training related expenses are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of $25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIH grants policies as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

The PD/PI should be an established investigator in the scientific area in which the application is focused and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be responsible for the selection and appointment of trainees to the approved research training program, and for the overall direction, management, administration, and evaluation of the program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required. The PD/PI has responsibility for the day to day administration of the program and is responsible for appointing members of the Advisory Committee (when applicable), using their recommendations to determine the appropriate allotment of funds.

The participation of multiple PDs/PIs is encouraged, particularly when each brings a unique perspective and skill set that will enhance training. For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy (//grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement*. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is programmatically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Preceptors/Mentors

Program faculty should have strong records as researchers, including recent publications and successful competition for research support in the area of the proposed research training program. Program faculty should also have a record of research training and mentoring, including successful, former trainees who have established productive careers relevant to the NIH mission. Programs are encouraged to build a diverse team of preceptors/mentors that includes, for example, faculty from underrepresented groups, women, and faculty at different career stages (i.e., junior as well as senior faculty). (See the Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).)

Trainees

The individuals to be trained must be citizens or noncitizen nationals of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=61131).

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the awarding unit, or when trainees are appointed to approved, short-term training positions.

Predoctoral Trainees

Predoctoral trainees must be enrolled in a program leading to a PhD or in an equivalent research doctoral degree program. Health-professional students who wish to interrupt their studies for a year or more to engage in full-time research training before completing their formal training programs, are also eligible.

Postdoctoral Trainees

Postdoctoral trainees must have received, as of the beginning date of the NRSA appointment, a PhD, MD, DDS, or comparable doctoral degree from an accredited domestic or foreign institution. Comparable doctoral degrees include, but are not limited to, the following: DMD, DC, DO, DVM., OD, DPM, ScD, EngD, DrPH, DNSc, DPT, PharmD, ND (Doctor of Naturopathy), DSW, PsyD, as well as a doctoral degree in nursing research. Documentation by an authorized official of the degree-granting institution certifying all degree requirements have been met prior to the beginning date of the training appointment is acceptable. Individuals in postgraduate clinical training, who wish to interrupt their studies for a year or more to engage in full-time research training before completing their formal training programs, are also eligible.

Short-Term Trainees

If requested, short-term trainees must be medical students, dental students, students in other health-professional programs, or graduate students in the physical or quantitative sciences. To be eligible for short-term, predoctoral research training positions students must be enrolled, in good standing, and must have completed at least one quarter or semester in a program leading to a clinical doctorate or a doctorate in a physical or quantitative science such as physics, mathematics, or engineering before participating in the training program. Individuals already matriculated in a formal research degree program in the health sciences, or those holding a research doctorate, a master's degree, or a combined health-professional/research doctorate normally are not eligible for short-term training positions. Within schools of pharmacy, only individuals who are candidates for the PharmD degree are eligible for short-term, research training positions.

Trainees selected for short-term training are required to pursue research training for 2-3 months on a full-time basis devoting at least 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Within the full-time training period, trainees must devote their time to the proposed research training and must confine clinical duties to those that are an integral part of the research training experience. Successful trainees may be appointed for additional periods of short-term training or, if appropriate to their career level, they should be encouraged to apply for an extended period of full-time training supported by an NRSA training grant or fellowship, or an NIH career development award.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Training (T) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations
All page limitations described in the SF424 (R&R) Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=61134) must be followed.

Instructions for Application Submission
The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover
Follow all instructions provided in the SF424 (R&R) Application Guide.

SF424(R&R) Project/Performance Site Locations
Follow all instructions provided in the SF424 (R&R) Application.

SF424 (R&R) Other Project Information
Follow all instructions provided in the SF424 (R&R) Application, with the following additional modifications:

Project Summary/Abstract: In the abstract, provide an overview of the program. Include the objectives, rationale, and design of the research training program. Highlight key activities in the training plan that promote skills development and successful transitions into careers in the biomedical research workforce. Indicate the planned duration of appointments, the projected number of trainees, including their levels (i.e., predoctoral, postdoctoral, short-term), and intended trainee outcomes.

Other Attachments. An Advisory Committee is not a required component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of such a committee to monitor progress of the training program. The composition, roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee members should be named in the application if they have been invited to participate at the time the application is submitted. Renewal applications with Advisory Committees should include the names of all committee members during the past project period. Name your file Advisory_Committee.pdf .

The filename provided for each Other Attachment will be the name used for the bookmark in the electronic application in eRA Commons.

SF424(R&R) Senior/Key Person Profile Expanded
Follow all instructions provided in the SF424 (R&R) Application. In addition:

Where applicable, personal statements should highlight prior experience with training and mentoring, promoting an inclusive and supportive scientific environment, and providing instruction in scientific rigor.

PHS 398 Cover Page Supplement
Follow all instructions provided in the SF424 (R&R) Application.

PHS 398 Training Subaward Budget Attachment(s)
Follow all instructions provided in the SF424 (R&R) Application Guide.

Training Budget
Follow all instructions provided in the SF424 (R&R) Application Guide, with the following additional modifications:

- Include all personnel other than the Training PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.

PHS 398 Research Training Program Plan
The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program Section
- Faculty, Trainees, and Training Record
- Other Training Program Sections
- Appendix - Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the FOA specifically instructs applicants to do so.

Follow all instructions provided in the SF424 (R&R) Application Guide with the following additional modifications:

Particular attention must be given to the required **Training Data Tables** (//grants.nih.gov/grants/guide/url_redirect.htm?id=61169). Applicants should summarize, in the body of the application, key data from the tables that highlight the characteristics of the applicant pool, faculty mentors, the educational and career outcomes of participants, and other factors that contribute to the overall environment of the program.

Training Program
Program Plan

Program Administration

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PDs/PIs) will promote the success of the trainees and training program. Multiple PDs/PIs are encouraged, particularly when each brings a unique perspective and skill set that will enhance training, as described in the Eligible Individuals (https://grants.nih.gov/grants/guide/pa-files/par-17-341.html#_Eligible_Individuals_(Program) section. The application should expand on the information in the biosketch(es) to address how the PD/PI or PD/PI team has:

- The scientific expertise, including a record of rigorous research, as well as the administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program.
- The time to commit sufficient effort to ensure the program's success, given other professional obligations (applicants should indicate the program director's percent effort in the proposed program).
- The planned strategy and administrative structure to oversee and monitor the program and ensure appropriate and timely trainee progress.

Program Faculty

In addition to the information specified in the Application Guide, describe:

- How the program faculty are trained to ensure the use of training and mentoring practices that promote the development of trainees from all backgrounds.
- How the program has a diverse team of program faculty, including faculty at a range of career stages and from a variety of scientific backgrounds.
- How the program faculty will provide supportive mentoring.
- In programs where trainees will have multiple mentors, how the faculty will effectively coordinate training and mentorship responsibilities.

Proposed Training

In addition to the information specified in the Application Guide, describe:

- How trainees will be instructed on data science principles that are relevant to their areas of research. Examples include statistics, computational science, bioinformatics, data sharing and access, data management, data security, and data privacy in human subjects research.

- Program activities intended to develop the working knowledge needed for trainees to select among and prepare for the next step in the varied research career options available in the biomedical workforce. For example, programs should provide all trainees with instruction and training in oral and written presentations and in skills needed to apply for individual fellowship or other grant support. All postdoctoral trainees should also be provided with instruction in laboratory and project management.
- For programs that propose short-term training, any didactic training must be well structured and appropriately justified for the duration of the training experience. Short-term trainees must have the opportunity to carry out supervised biomedical, behavioral, or clinical research with the primary objective of developing or enhancing their research skills and knowledge in preparation for a health-related research career.
- For renewal applications, highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge or educational practices.

Training Program Evaluation

In addition to the information specified in the Application Guide, describe:

- How the proposed evaluation will assess the extent to which trainees find the training program to be inclusive and supportive of trainee development.
- The program's procedures for responding to program evaluation findings.

Trainee Candidates

Through the narrative and summaries of the information presented in the Training Data Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and the attachments, the application should::

- Provide a strong justification for the number of requested trainee positions.
- Expand upon the recruitment plan to enhance diversity and explain how it will identify and recruit a diverse group of candidates from a wide variety of institution types and backgrounds as described in NIH's Notice of Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

Institutional Environment and Commitment to Training

The application should describe how the level of institutional and departmental commitment to research and training excellence will promote the success of the trainees and training program. For institutions that have multiple NIH-funded training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones. A letter providing assurances of the institutional commitment should be provided in the Letters of Support section of the application. Detailed instructions on the types of support are found below in the Letters of Support section of the FOA.

Recruitment Plan to Enhance Diversity

The applicant must provide a recruitment plan to enhance diversity. Include outreach strategies and activities designed to recruit prospective trainees from diverse backgrounds, e.g. those from groups described in the Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html). Describe the specific efforts to be undertaken by the training program and how these might coordinate with trainee recruitment efforts of the medical school(s), graduate school(s), and/or the institution(s). Training grant program faculty are expected to be actively involved in recruitment efforts.

Plan for Instruction in the Responsible Conduct of Research

Individuals are required to comply with the instructions for Plan for Instruction in the Responsible Conduct of Research as provided in the SF424 (R&R) Application Guide. This includes the following: Describe how the Responsible Conduct of Research (RCR) components are well integrated into the overall training plan, including instruction at multiple stages of trainee careers and in a variety of formats and contexts. Where applicable, explain how instruction in RCR synergizes with elements of the curriculum designed to enhance trainees abilities to conduct rigorous and reproducible research. Describe how all participating faculty will reiterate and augment key elements of responsible conduct when trainees are performing mentored research projects.

Plan for Instruction in Methods for Enhancing Reproducibility

Individuals are required to comply with the instructions for the Plan for Instruction in Methods for Enhancing Reproducibility as provided in the SF424 (R&R) Application Guide, which include a description of how the program will provide training in scientific reasoning, rigorous research design, relevant experimental methods, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, quantitative approaches, and data analysis and interpretation, as appropriate to the field of study and the level and prior preparation of the trainees.

Progress Report for Renewal Applications

For renewal applications, highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program.

Faculty, Trainees, And Training Record Section

Participating Faculty Biosketches

Program faculty are encouraged to provide a personal statement that describes their prior experience with:

- Training, mentoring, and promoting an inclusive and supportive scientific environment.
- Providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.
- Aiding and supporting trainees in identifying and transitioning into careers in the biomedical research workforce that are consistent with trainees' skills, interests, and values.

Letters of Support

Institutional Support Letter. The application must include a signed letter on institutional letterhead from a President, Provost, Dean or key institutional leader that describes the activities and resources provided by the institution that will ensure the success of the planned training program and its trainees (not to exceed 10 pages). Institutional commitment to the following areas should be described in the letter:

- Developing and promoting a culture in which the highest standards of scientific rigor, reproducibility and responsible conduct are advanced.
- Ensuring sufficient resources and support will be available to the training faculty and trainees, for example, to permit early stage faculty to participate in training and trainees to continue in training if their mentors experience a hiatus in research funding.
- Supporting core facilities and technology resources and describing how they can be used to enhance training.
- Providing adequate staff, facilities, and educational resources to the planned program.
- Supporting the PDs/PIs and other key staff associated with the planned training program; ensuring faculty have protected time available to devote to mentoring, training and research; considering activities integral to excellent training (such as teaching and mentorship) in tenure and promotion decisions.
- Promoting diversity and inclusion at all levels of the research training environment (trainees, staff, faculty, and leadership); ensuring the research facilities and laboratory practices promote the safety of trainees; ensuring the research facilities are accessible to trainees with disabilities; ensuring a positive, supportive and inclusive research and training environment for individuals from all backgrounds.
- Ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (NOT-OD-19-056 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-056.html)) or OCR (e.g., see NOT-OD-15-152 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-152.html)).

- Providing the types and levels of support necessary for trainees to successfully complete the research training program.
- Supporting evaluation of the training program and procedures for responding to evaluation findings.

All information related to institutional support, as defined above, must be included within the 10-page limit of this letter.

Appendix

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to theSF424 (R&R) Application Guide instructions.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120). The National Research Service Award (NRSA) policies (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Requests of $500,000 or more for direct costs in any year

Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide. Applicants are advised to refer to Agency Contacts for exceptions.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will produce a diverse pool of well-trained scientists with the skills necessary to conduct rigorous and reproducible research. The overall impact score should reflect reviewers assessment of the likelihood that the proposed training program will prepare individuals for successful, productive scientific research careers and thereby exert a sustained influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the training program, and give a separate score for each. When applicable, the reviewers will consider relevant questions in the context of proposed short-term training. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Training Program and Environment

- Are the research facilities and research environment conducive to preparing trainees for successful careers as biomedical research scientists?
- Are the objectives, design and direction of the proposed research training program likely to ensure effective training?
- Does the application describe an effective strategy and administrative structure to oversee and monitor the program to ensure appropriate and timely trainee progress?
- Do the courses, where relevant, and research experiences provide opportunities for trainees to acquire skill and expertise in transparent, rigorous and reproducible research methodologies and tools applicable to the goals of the training program, including relevant areas of data science?
- Does the program provide appropriate inter- or multidisciplinary research training opportunities?
- Is the proposed training program likely to ensure trainees will be well prepared for research-intensive and research-related careers?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to ensure the success of the program?
- Is it clear how the proposed training program is distinguished from other externally funded training programs at the institution?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Does the PD/PI, and where relevant, multiple PDs/PIs, have the scientific expertise, including a record of rigorous research, administrative, and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Does the PD/PI, and where relevant, multiple PD/PIs, plan to commit sufficient effort to ensure the program's success?
- **For applications designating multiple PDs/PIs:**
  - Is a strong justification provided that the multiple PD/PI leadership approach will benefit the training program and the trainees?
  - Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the training program and the complementary expertise of the PDs/PIs?

Preceptors Mentors

- Are sufficient numbers of experienced preceptors/mentors with appropriate expertise and funding available to support the number and level of trainees (including short-term trainees, if applicable) proposed in the application?
- Do the preceptors/mentors have strong records as researchers, including recent publications and successful competition for research support in areas directly related to the proposed research training program?
- Do the preceptors/mentors have strong records of training and effective and supportive mentoring of individuals at the level of trainees proposed in the program (including short-term trainees, if applicable)? Are appropriate plans in place to ensure that preceptors with less former research training experience will be provided with guidance on how to provide strong and successful mentoring?
- Is there a diverse team of program faculty, including faculty at a range of career stages and from a variety of scientific backgrounds?
- If the program will support clinical trial research experience for the trainees, do the mentor(s) who will supervise the trainee(s) have the expertise, experience, resources, and ability to provide appropriate guidance and help the trainee(s) to meet the timelines?

Trainees

- Is a recruitment plan proposed with strategies likely to attract well-qualified trainees for the training program?
- Is there a competitive applicant pool of sufficient size and quality, at each of the proposed levels (predoctoral, postdoctoral and/or short-term), to ensure a successful training program?
- Does the application provide a strong justification for the number of trainee positions requested?
- Are there well-defined and justified selection and re-appointment criteria as well as retention strategies?

Training Record

- How successful are the trainees (or, for new applications, other past students/postdoctorates in similar training) in completing the program?
- Has the training program ensured that trainees are productive (or, for new applications, other past students/postdoctorates in similar training) in terms of research accomplishments, publication of research conducted during the training period, and subsequent training appointments and fellowship or career development awards?
- How successful are the trainees (or, for new applications, other past students/postdoctorates in similar training) in achieving productive scientific careers as evidenced by successful competition for research science positions in industry, academia, government, or other research venues; grants; receipt of honors, awards, or patents; high-impact publications; promotion to scientific leadership positions; and/or other such measures of success?
- To what extent do trainees subsequent positions in industrial, academic, government, non-profit, or other sectors benefit from their NRSA-supported research training and directly benefit the broader biomedical research enterprise?
- Does the program propose a rigorous evaluation plan to assess the quality and effectiveness of the training? Are effective mechanisms in place for obtaining the views of current and former trainees, including feedback about the training environment?
  - **For applications that propose to train health professionals,** is there a record of retaining health professional trainees in research training or other research activities for at least two years?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Training in Methods for Enhancing Reproducibility

Does the plan for Instruction in Methods for Enhancing Reproducibility describe how trainees will receive training in scientific reasoning, rigorous research design, relevant experimental methods, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, quantitative approaches, and data analysis and interpretation, appropriate to field of study and the level and prior preparation of the trainees?

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

For Renewals, the committee will consider the progress made in the last funding period, including on the Recruitment Plan to Enhance Diversity, and Training in the Responsible Conduct of Research. Does the application describe the program's accomplishments over the past funding period(s)? Is the program achieving its training objectives? Has the program evaluated the quality and effectiveness of the training experience (and when applicable, short-term training experience), and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon? Are changes proposed that are likely to improve or strengthen the research training experience during the next project period (may not be applicable to short-term training)? Does the program continue to evolve and reflect changes in the research area in which the training occurs?

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific aspect of the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Recruitment Plan to Enhance Diversity

Peer reviewers will separately evaluate the recruitment plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of prospective individuals from underrepresented groups. The plan will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the consensus of the review committee will be included in an administrative note in the summary statement.

Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) ***Format -*** Does the plan satisfactorily address the format of instruction, e.g., lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (*A plan involving only on-line instruction is not acceptable.*); 2) ***Subject Matter*** Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics? 3) ***Faculty Participation -*** Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) ***Duration of Instruction -*** Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) ***Frequency of Instruction*** Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

For renewal applications, does the progress report document acceptable RCR instruction in the five components described above? Does the plan describe how participation in RCR instruction is being monitored? Are appropriate changes in the plan for RCR instruction proposed in response to feedback and in response to evolving issues related to responsible conduct of research?

Plans and past record will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the summary statement will provide the consensus of the review committee.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the sponsoring Institute or Center in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (https://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html).

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov). For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html); https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf (https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant s integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the *NIH Grants Policy Statement* - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=61170).

The taxability of stipends is described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171). Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171).

As specified in the NIH Revitalization Act of 1993, Kirschstein-NRSA recipients incur a service payback obligation for the first 12 months of postdoctoral support. Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171); and more details are in the Frequently Asked Questions (//grants.nih.gov/grants/guide/url_redirect.htm?id=61174). Officials at the grantee institution have the responsibility of explaining the terms of the payback requirements to all prospective trainees before appointment to the training grant. Additionally, all trainees recruited into the training program should be provided with information related to the career options that might be available when they complete the program. The suitability of such career options as methods to satisfy the NRSA service payback obligation should be discussed.

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not applicable.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the grantee institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

Other Reporting Requirements

- The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.htm?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Grantees must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.htm?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.
- Additionally, a completed Payback Agreement Form (PHS Form 6031 (//grants.nih.gov/grants/guide/url_redirect.htm?id=41181)) must be submitted for each postdoctoral trainee in his or her first 12 months of support.
- A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.htm?id=61189)). Individuals with a Conditional Permanent Resident status must first meet full (non-conditional) Permanent Residency requirements before receiving support.
- Termination Notice: Within 30 days of the end of the total support period, the institution must submit a Termination Notice (PHS Form 416-7 (//grants.nih.gov/grants/guide/url_redirect.htm?id=41179)) via xTrain (//grants.nih.gov/grants/guide/url_redirect.htm?id=41183) for each trainee appointed for eight weeks or more. Trainees with service payback requirements must notify the NIH of any change in address and submit Annual Payback Activities Certification Forms (PHS Form 6031-1 (//grants.nih.gov/grants/guide/url_redirect.htm?id=41180)) until the payback service obligation is satisfied.

A final RPPR, the expenditure data portion of the Federal Financial Report, and Termination Notices for all Trainees, are required for closeout of an award as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 Award Term and Conditions for Recipient Integrity and Performance Matters.

4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Because of the difference in individual Institute and Center (IC) program requirements for this FOA, prospective applications **MUST** consult the **Table of IC-Specific Information, Requirements, and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/nrsa-institutional-research-training-grant-parent-t32.html)**, to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

Application Submission Contacts

eRA Commons Help Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)
Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

See: **Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/nrsa-institutional-research-training-grant-parent-t32.html)**

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

See: **Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/nrsa-institutional-research-training-grant-parent-t32.html)**

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Section 487 of the Public Health Service Act as amended (42 USC 288) and under Federal Regulations 42 CFR 66.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?03-20-20)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

NIH National Institutes of Health (/grants/oer.htm)
Office of Extramural Research

(https://www.hhs.gov/) Department of Health and Human Services (HHS)

USA.gov (https://www.usa.gov/)

NIH... Turning Discovery Into Health®

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF APHA MEMBER 9

I, Jesus Ramirez-Valles, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. I am the Division Chief of the Division of Prevention Science and Professor of Medicine in the Department of Medicine at the University of California San Francisco (UCSF). My work focuses on the challenges of health and healthcare for excluded communities including LGBTQ+ populations, people of color, women, and people living with HIV. My current work researches the extent to which structural racism and discrimination shapes older gay men's health.

2. I am offering this declaration in my individual capacity and not on behalf of my employer.

3. My interest in this area of research began during my work as a community organizer near El Paso, Texas during the HIV/AIDS epidemic in the 1980s, when I took care of countless LBGTQ+ individuals—including friends—as they died from HIV/AIDS. After that harrowing experience, I wanted to dedicate my career to learning how to prevent those harms in the future, and I discovered my passion for using research to advocate for the unmet health and healthcare

needs of excluded communities. Beginning early in my career, I began to study the particular harms of homophobia, racism, and stigma that Latine LGBTQ+ communities felt.

4. Prior to working at the University of California San Francisco, I served as the director of the Healthy Equity Institute at San Francisco State University. Before that, I chaired the department of Community Health Sciences at the University of Illinois-Chicago School of Public Health, where I was a professor of public health for 22 years.

5. I received my B.A. in Communications from the Monterrey Institute of Technology and Higher Education in 1988. I received my master's degree in 1993 and my PhD in 1997 in public health at the University of Michigan, where I studied the intersection of community organizing and public health issues such as reproductive maternal and child health and substance abuse prevention.

6. To date, I have published at least 46 peer-reviewed journal articles and 2 scholarly books made possible, in large part, through significant research funding by NIH.

7. I am a dues-paying member of the American Public Health Association (APHA).

8. I have applied for and received 17 grants from the NIH over the course of my career. The application process for each of those grants required months, if not years, of preparation to ensure that the proposal would yield impactful research according to high standards through the rigorous NIH review process. To prepare each application, I completed significant preparation work including pilot research to assess feasibility, literature review, assembling a team including community partners, development of the research plan, and creating a prospective budget. On average, it takes at least one year to prepare. In my experience, the NIH review process involves an iterative series of communications with NIH officials to ensure my grants align with the priorities of the agency and the goals of the funding announcement.

9. Prior to March 2025, I successfully renewed my grant funding every year without issue. To do so, I submitted a progress report, and our funding was disbursed without disruption.

10. But since March 2025, NIH has terminated at least two grants that supported my research. For each of these grants, NIH stated in a termination notice that the project "no longer effectuates agency priorities." The total amount awarded originally across those two grants is over $3.6 million.

11. One of those terminated grants is a project-based R01 grant awarded by the National Institute on Aging beginning on September 15, 2022. A true and correct copy of the notice of award (NOA) for that grant is attached hereto as Exhibit A. That grant—titled *Structural Racism and Discrimination in Older Men's Health Inequities* (Project Number 5R01AG077934)—originally had a total award value of approximately $3.25 million. *See* Ex. A.

12. The goal of this project was to shed light on the extent and the manner in which structural racism and discrimination shapes the health of older gay men (*i.e.*, over the age of 55). More specifically, our goal was to better understand how gay men's life experiences involving exodus from hostile environments (such as communities or work places) and the formation of support communities defined their long-term health prospects. This is important because older gay men's health (including HIV) fares worse than that of their heterosexual counterparts, as they experience higher structural discrimination and have less access to supportive resources on average. The grant aimed to assess the relationships among health, stigma, structural racism and discrimination, resources, and biomarkers of health and aging in older gay men to better understand the reasons for the disparity in health outcomes relative to similarly situated heterosexual men. This population has been historically understudied in aging research because, prior to this cohort, we did not have many older LGTBQ+ people, and because the HIV/AIDS

epidemic claimed the lives of so many gay men before they reached older adulthood, limiting the opportunity for study until now.

13. This project took the form of a study in the San Francisco Bay Area. The project originally aimed to recruit 600 older gay men from whom we would collect structural data (*i.e.*, about the community in which the subject lived), individual data (*i.e.*, about the social, economic and medical background of the subject), and biological data (*i.e.*, blood samples). We intended to use these data to test hypotheses about associations between structural discrimination, resources, and health (including mental health, HIV risk and treatment, and cognitive function) of older gay men. For example, we could study the biomarkers in blood samples to see the longterm effects of stress and trauma. Ultimately, the data and findings from this study were intended to constitute the baseline to demonstrate how different factors including HIV status, medications taken, race, and place of residence, could have long-term effects on the body as it aged. This data could be used for the basis of a longitudinal study tracking participants to continue to understand queer aging in more particular ways.

14. I designed the study in response to NIH's Request for Applications (RFA) titled "Understanding and Addressing the Impact of Structural Racism and Discrimination and Minority Health and Health Disparities." A true and correct copy of that RFA, last accessed April 23, 2025, is attached hereto as Exhibit B. The RFA states that the funding opportunity purpose is to "support (1) observational research to understand the role of structural racism and discrimination [] in causing and sustaining health disparities, and (2) intervention research that addresses [structural racism and discrimination] in order to improve minority health or reduce health disparities." Ex. B at 1. According to the RFA, "[p]rojects must address [structural racism and discrimination] in one or more NIH-designated populations with health disparities in

the US and should address documented disparities in health outcomes." *Id.* at 3. Among those NIH-designated populations with health disparities are "[r]acial and ethnic minorities" and "sexual and gender minorities in the U.S." *Id.* at 1. The study also attends to the NIH Office of AIDS Research Strategic Plan of addressing HIV comorbidities, complications, and health disparities.

15. I spent a significant amount of time curating and successfully explaining the project's relevance to structural discrimination in order to meet the funding program's stated objective. I began to develop the study over fifteen years ago as we began to witness and experience the first generation of HIV positive people living long enough to age. First, I conducted pilot research and a literature review, through which I published a book and a couple of articles about queer aging. After the publications, it took roughly one year for my team and I to develop our initial proposal. Over the following years, I submitted several versions of the application to NIH and refined the application in response to NIH reviews to highlight the public health significance of studying HIV and aging, incorporated the emerging biomarkers, and centered the project in San Francisco – a city with deep ties to the history of the HIV epidemic and a large population of individuals living with HIV. The NIH grant was awarded in 2022.

16. Prior to March 2025, NIH officials never raised any concerns to me about this grant during those renewal reviews, and the NIH Office of AIDS Research featured the project as an exemplar project. In fact, just last year, NIH approved a supplemental grant for the project.

17. This grant was originally supposed to end in 2026. However, on March 21, 2025, NIH issued a termination notice stating that the grant had been terminated. A true and correct copy of this termination notice is attached hereto as Exhibit C. Prior to this notice, there was never any indication that this grant was in jeopardy. Three days later, on March 24, 2025, I also received a

revised NOA reflecting the termination of the grant and echoing the language of the termination notice. A true and correct copy of the revised NOA is attached hereto as Exhibit D.

18. Neither the revised NOA nor the termination notice includes any individualized explanation for why the grant was cancelled, and both fail to discuss any of the data or analysis from our application, annual progress reports, or other related material. Instead, the termination notice includes the following language about its decision:

> This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Ex. C at 2; *see also* Ex. D at 5-6.

19. The termination notice also states that, although "'NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,' no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities." Ex. C. at 2.

20. I do not understand what the notice means by "amorphous equity objectives" or "diversity, equity, and inclusion" or "DEI." I also do not understand why NIH believes that this project is based on "artificial and non-scientific categories" or that it does "not enhance health, lengthen life, or reduce illness." I also am uncertain why NIH believes this project does not effectuate agency priorities.

21. This termination will severely hinder our ability to complete our study and develop recommendations based on any findings. The study had recruited only approximately three hundred (300) of the six hundred (600) intended participants. Of those participants, several selected for a qualitative data collective interview had not completed the full study at the time of termination. This sample size is not large enough to offer scientifically valid hypotheses (*e.g.*, such that an analysis could determine any associations between biomarkers and other variables in the study, such as racial or HIV status). The supplement to the project to study transgender women had recruited only fifteen (15) of the one hundred fifty (150) intended participants. For those participants mid-study or yet to be recruited, the time to collect data is of the essence, as participants by their nature are of older age. In addition, rebuilding the recruitment process will take significant start up time and effort.

22. The termination also harms our relationships with community members and partners. Recruiting participants for the study required building relationships and contacts within the community. The abrupt termination of the project harmed the trust we built with community partner organizations and members of the community who participated in the study.

23. The project had a staff of seven UCSF members including myself, one at San Francisco State University, one at Tulane University, and one at the University of Alabama. Because of the termination of this grant and the other grant terminated by NIH, I will likely have to lay off at least two staff members. These lost grants also accounted for approximately 20% of my salary, and although I am currently relying on reserve funding to make up the difference, I do not believe that will be a long-term solution for that loss. Several other co-investigators, including the three team members at our partner institutions and one at UCSF, will also be at risk of losing a portion of their salaries.

24. As we are witnessing the first generation of people with HIV living to reach old age, we also have our first opportunity to study how aging is affected by HIV, related medications, and other factors like discrimination. If studies like mine are unable to continue, we will lose a cohort of aging people and their experiences, as well as the opportunity to learn from them. Investigating how social and medical factors affect aging people from communities not often studied can directly lead us to answers about how those people can live longer. Such studies also help inform the body of science generally around how people age.

25. I have suffered substantial emotional distress about the termination of this project. This work was the culmination of a career-long effort to use public health research to help LGBTQ+ populations, especially those affected by the HIV/AIDS epidemic that I myself witnessed firsthand.

26. On April 7, 2025, we filed an appeal for the grant termination. I submitted an appeal for the grant because I do not anticipate being able to find replacement funding for the projects. But I also do not understand why the grant was terminated, and I had no idea how to address any agency concerns or recharacterize or revise my project for the purposes of appeal, especially in light of the lack of information provided by NIH. I also do not know how to submit new proposals in light of the vagueness of this language and in light of my current research portfolio and goals.

27. I received a substantially similar termination notice for another grant that supports my work (Project Number 1R01MD020284—Measures of Structural Stigmatization and Discrimination for HIV Research with Latine Sexual and Gender Minorities). NIH issued that termination on March 12, 2025. A true and correct copy of that termination notice is attached hereto as Exhibit E. Among other identical language, this notice uses the exact same paragraph

to explain the agency's decision to cut this grant, including that the "award no longer effectuates agency priorities." Ex. E at 1. An appeal for this grant was submitted, but I have the same concerns with this appeal as I do with the appeal described above.

28. I do not know whether any appeal has any chance of success, given the following language across the termination notices I received: "The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities."

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 24 day of April, 2025.

Jesus Ramirez-Valles

EXHIBIT A

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG077934
Federal Award Date
09-09-2022

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, THE
1855 FOLSOM ST STE 425

SAN FRANCISCO, 94143

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1946036493A6

4. Employer Identification Number (EIN)
946036493

5. Data Universal Numbering System (DUNS)
094878337

7. Recipient's Unique Entity Identifier
KMH5K9V7S518

q. Project Director or Principal Investigator
Jesus Ramirez-Valles, PHD
Professor And Director
jesus.ramirez-valles@ucsf.edu
415-405-4350

8. Authorized Official
Estrella Garcia
estrella.garcia@ucsf.edu
415-260-5128

Federal Agency Information

9. Awarding Agency Contact Information
Lesa McQueen

NATIONAL INSTITUTE ON AGING
lesa_mcqueen@nih.gov
301-496-1472

10. Program Official Contact Information
Melissa S Gerald
Health Science Administrator
NATIONAL INSTITUTE ON AGING
geraldmel@nia.nih.gov
301-402-4156

Federal Award Information

11. Award Number
1R01AG077934-01

12. Unique Federal Award Identification Number (FAIN)
R01AG077934

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Structural Racism and Discrimination in Older Men's Health Inequities

15. Assistance Listing Number
93.866

17. Assistance Listing Program Title
Aging Research

1q. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09-15-2022 **– End Date** 05-31-2023	
20. Total Amount of Federal Funds Obligated by this Action	$844,201
20 a. Direct Cost Amount	$526,667
20 b. Indirect Cost Amount	$317,534
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$844,201
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$844,201
27. Project Period Start Date 09-15-2022 **– End Date** 05-31-2026	
2q. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$844,201

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Ryan Blakeney

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Version:11 - 7/14/2022 8:27 PM | Generated on: 9/9/2022 12:06 AM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1R01AG0qq934-01

Principal Investigator(s):
Jesus Ramirez-Valles, PHD

Award e-mailed to: cgrasteam@ucsf.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $844,201 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Regents of the UCSF in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG077934. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Ryan Blakeney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

A1160

Version: 11 - 7/14/2022 8:27 PM | Generated on: 9/9/2022 12:06 AM

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$279,042
Fringe Benefits	$108,812
Personnel Costs (Subtotal)	$387,854
Materials & Supplies	$11,310
Travel	$14,442
Other	$33,149
Subawards/Consortium/Contractual Costs	$77,912
Publication Costs	$2,000
Federal Direct Costs	$526,667
Federal F&A Costs	$317,534
Approved Budget	$844,201
Total Amount of Federal Funds Authorized (Federal Share)	$844,201
TOTAL FEDERAL AWARD AMOUNT	$844,201
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$844,201

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$844,201	$844,201
2	$807,774	$807,774
3	$800,878	$800,878
4	$798,781	$798,781

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1946036493A6
Document Number: RAG077934A
PMS Account Type: P (Subaccount)
Fiscal Year: 2022

IC	CAN	2022	2023	2024	2025
AG	8470694	$844,201	$807,774	$800,878	$798,781

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 2BPDIGE / **OC**: 41021 / **Released**: Blakeney, Ryan 08-31-2022
Award Processed: 09/09/2022 12:06:07 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AG0qq934-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01AG0qq934-01

A1161

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG077934. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in

the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 1R01AG0qq934-01

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION: The present award is being made without a currently valid certification of IRB approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects, including recruitment, may be conducted pending the National Institute on Aging's acceptance of the certification of IRB approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to the National Institute on Aging's notification to the grantee that the identified issues have been resolved and this restriction removed.

Failure to respond within the 60-day period and/or to otherwise comply with the above requirements may result in suspension and/or termination of this award, audit/or disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, Chapter 4.1.15 Human Subjects Protections (http://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm), for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

_____

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

This award includes funds awarded for consortium activity with SAN FRANCISCO STATE UNIVERSITY in the amount of $21,179 ($13,664 direct costs + $7,515 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:
http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15_consortium_agreements.htm

This award includes funds awarded for consortium activity with University of Alabama at Birmingham in the amount of $21,381 ($14,398 direct costs + $6,983 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:

http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15consortium_agreements.htm

This award includes funds awarded for consortium activity with University of Tulane Univ. School of Public Health and Tropical Medicine in the amount of $35,352 ($23,258 direct costs + $12,094 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15consortium_agreements.htm

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle each year on 06/01. The Research Performance Progress Report (RPPR) is due 45 days prior to this date for SNAP awards or 60 days prior for non-SNAP awards.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AG077934-01

INSTITUTION: The Regents of the UCSF

Budget	Year 1	Year 2	Year 3	Year 4
Salaries and Wages	$279,042	$260,538	$273,776	$299,238
Fringe Benefits	$108,812	$100,489	$105,332	$113,354
Personnel Costs (Subtotal)	$387,854	$361,027	$379,108	$412,592
Materials & Supplies	$11,310	$480	$480	$480
Travel	$14,442	$25,760	$20,558	$13,194
Other	$33,149	$71,155	$50,150	$11,052
Subawards/Consortium/Contractual Costs	$77,912	$59,197	$69,146	$86,859
Publication Costs	$2,000	$2,260	$2,789	$3,500
TOTAL FEDERAL DC	$526,667	$519,879	$522,231	$527,677
TOTAL FEDERAL F&A	$317,534	$287,895	$278,647	$271,104
TOTAL COST	$844,201	$807,774	$800,878	$798,781

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4
F&A Cost Rate 1	61.5%	61.5%	61.5%	61.5%
F&A Cost Base 1	$516,315	$468,122	$453,085	$440,819
F&A Costs 1	$317,534	$287,895	$278,647	$271,104

EXHIBIT B

This notice has expired. Check the NIH Guide (https://grants.nih.gov/funding/searchguide/) for active opportunities and notices.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Institute on Minority Health and Health Disparities (NIMHD (https://www.nimhd.nih.gov/))

National Eye Institute (NEI (https://www.nei.nih.gov/))

National Heart, Lung, and Blood Institute (NHLBI (https://www.nhlbi.nih.gov/))

National Human Genome Research Institute (NHGRI (https://www.genome.gov/))

National Institute on Aging (NIA (https://www.nia.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))

National Institute of Allergy and Infectious Diseases (NIAID (https://www.niaid.nih.gov/))

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS (https://www.niams.nih.gov/))

National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://www.nibib.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (https://www.nichd.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))

National Institute of Dental and Craniofacial Research (NIDCR (https://www.nidcr.nih.gov/))

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/))

National Institute on Drug Abuse (NIDA (https://www.drugabuse.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

National Institute of General Medical Sciences (NIGMS (https://www.nigms.nih.gov/))

National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml))

National Institute of Neurological Disorders and Stroke (NINDS (https://www.ninds.nih.gov/))

National Institute of Nursing Research (NINR (https://www.ninr.nih.gov/))

National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))

National Cancer Institute (NCI (https://www.cancer.gov/))

Office of The Director, National Institutes of Health (OD (https://www.nih.gov/institutes-nih/nih-office-director))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention (ODP (https://prevention.nih.gov/))

Office of Behavioral and Social Sciences Research (OBSSR (https://obssr.od.nih.gov/))

Sexual and Gender Minority Research Office (SGMRO (https://dpcpsi.nih.gov/sgmro))

Office of Research on Women's Health (ORWH (https://orwh.od.nih.gov/))

Funding Opportunity Title

Understanding and Addressing the Impact of Structural Racism and Discrimination on Minority Health and Health Disparities (R01 Clinical Trial Optional)

Activity Code

R01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant

Announcement Type

New

Related Notices

EXPIRED

- **April 23, 2021** - Notice of Pre-Application Technical Assistance Webinar for RFA-MD-21-004. See Notice NOT-MD-21-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-MD-21-018.html).

Funding Opportunity Announcement (FOA) Number

RFA-MD-21-004

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.307, 93.855, 93.172, 93.273, 93.399, 93.867, 93.866, 93.846, 93.242, 93.113, 93.865, 93.286, 93.310, 93.121, 93.279, 93.213, 93.853, 93.173, 93.859, 93.361, 93.313, 93.837, 93.838, 93.839, 93.840, 93.233, 93.847

Funding Opportunity Purpose

This initiative will support (1) observational research to understand the role of structural racism and discrimination (SRD) in causing and sustaining health disparities, and (2) intervention research that addresses SRD in order to improve minority health or reduce health disparities.

Key Dates

Posted Date

March 23, 2021

Open Date (Earliest Submission Date)

July 20, 2021

Letter of Intent Due Date(s)

July 20, 2021

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
August 24, 2021	Not Applicable	August 24, 2021	November 2021	January 2022	April 2022

All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date

August 25, 2021

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000),except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Table of Contents

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Key Definitions for the FOA:

Discrimination: A socially structured action that is unfair or unjustified and harms individuals and groups. Discrimination can be attributed to social interactions that occur to protect more powerful and privileged groups or institutions at the detriment of other groups. Racism refers to discrimination based on race or ethnicity.

Structural discrimination refers to macro-level conditions (e.g., residential segregation) that limit opportunities, resources, and well-being of less privileged groups (Healthy People 2020, https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/discrimination (https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/discrimination)).

Structural racism and discrimination (SRD): For the purposes of this FOA, SRD refers to structural discrimination on the basis of race/ethnicity and/or other statuses, including but not limited to gender, sexual orientation, gender identity, disability status, social class or socioeconomic status, religion, national origin, immigration status, limited English proficiency, or physical characteristics or health conditions.

NIH-designated Populations with Health Disparities: Racial and ethnic minorities, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities in the U.S. (see https://www.nimhd.nih.gov/about/overview/ (https://www.nimhd.nih.gov/about/overview/)).

Background

There is increasing recognition that racism and discrimination contribute to poorer health outcomes for racial/ethnic minorities and other populations that experience health disparities. In fact, all populations with health disparities experience increased exposure to racism and/or other forms of discrimination over the life course. There is also a growing societal recognition that racism and discrimination extend beyond the behavior of individuals to include SRD, which is embedded in historical societal, institutional, organizational and governmental structures through formal and informal processes, procedures, and practices that limit both opportunities and resources to segments of the population. SRD is supported by the power structures that exist in society and in the institutions that are most likely to influence health outcomes.

Despite this enhanced awareness, racism and discrimination are not routinely included as determinants of health in biomedical research. Health research on racism and discrimination to date has largely focused on interpersonal interactions, and to a lesser extent, one specific form of SRD, residential segregation. Typically, such research focuses on the adverse health consequences of SRD exposures. Less research has explored the resilience among populations exposed to SRD or community strategies to resist or mitigate historic or contemporary SRD exposures. Additionally, intervention research has rarely emphasized reduction of SRD as a strategy to improve health and reduce disparities. Research on mitigation of SRD is needed to inform health care and social policies at all levels.

Health research and interventions need to routinely incorporate constructs and measurement of SRD across multiple socioecological domains and levels of influence in order to improve minority health, promote health equity, and eliminate health disparities (see the NIMHD Research Framework for more information: https://www.nimhd.nih.gov/about/overview/research-framework.html (https://www.nimhd.nih.gov/about/overview/research-framework.html)). Examples of domains in which SRD may occur include, but are not limited to, the following:

- Organizational/Institutional: Organizational-level climate; workplace hiring, promotion, or disciplinary practices; academic tracking, stigmatization, school disciplinary and admission practices; tolerance of abuse/harassment; health care system practices.
- Neighborhood/Community: Housing or lending practices and property value assessments; zoning laws; neighborhood distribution of public transportation, green spaces, grocery stores, hospitals and emergency departments, ambulatory health clinics, resource allocation for schools through local tax base, location of cellular towers, highways and major thoroughfares, and industrial or waste sites; criminal justice profiling; targeted social marketing of harmful or ineffective products; hate crimes.
- Societal: Criminal justice policies and sentencing practices, land/water use rights, self-governance or political representation for tribal communities and US territories, immigration and asylum policies and procedures, gerrymandering, voter suppression laws or practices, religious and cultural discrimination, depiction or representation in national media and social media.

Research Objectives

This initiative will support observational or intervention research to understand and address the impact of SRD on minority health and health disparities.

Projects must address SRD in one or more NIH-designated populations with health disparities in the US and should address documented disparities in health outcomes. Applications are expected to provide a justification for why the specific types of SRD included constitute SRD, such as how the racism or discrimination is structural rather than reflecting individual-level behavior and how the SRD results in differential treatment or outcomes for less advantaged individuals, groups or populations. For example, with a project examining discriminatory school disciplinary practices, documentation of different overall rates of student suspensions or expulsions by race/ethnicity would not be sufficient to label this pattern as SRD. However, different rates of student suspensions or expulsions by race/ethnicity for the same type of student behavior or violation could be evidence of SRD. Applications are also expected to **provide a conceptual model** identifying hypothesized pathways between the SRD and health outcomes. Potential health outcomes may reflect health status; health condition-specific or all-cause disability, quality of life, mortality and morbidity; biological measures that reflect cumulative exposures to and effects of SRD; health behaviors; or access to, utilization of, or quality of health care.

It is also expected that projects will collect data on SRD beyond individual self-reported perceptions and experiences to include data at organizational, community or societal levels. Potential data sources for SRD may include but are not limited to U.S. Census data, birth and mortality records; health surveillance data; crime statistics; traditional and social media data, school-based or educational data; labor statistics; voting records; local, state, and Federal law and policies; home ownership covenants; and organizational/institutional mission statements, policy guidance, operating procedures, or other relevant documents.

Projects are expected to involve collaborations with relevant organizations or groups or stakeholders, such as academic institutions, health service providers and systems, state and local public health agencies or other governmental agencies such as housing and transportation, criminal justice systems, school systems, patient or consumer advocacy groups, community-based organizations, and faith-based organizations. Multidisciplinary research teams, including researchers from areas outside of the health sciences, such as economics, education, history, criminology, law, and political science, are encouraged.

Observational Studies: Projects may (1) examine the impact of SRD on health, and/or (2) evaluate the impact that existing efforts to address SRD (e.g., laws, policies, programs, organizational practices and procedures) have on the health of individuals, families, and communities. Projects may involve collection of primary data/and or analysis of existing data and may involve quantitative or mixed methods approaches. Projects must be exclusively domestic, including U.S. territories. Projects using longitudinal designs or multiple sites are strongly encouraged, as are projects examining resilience in the face of exposure to SRD.

Intervention Studies: Projects may focus on health promotion, treatment, and/or prevention. Interventions may focus primarily on addressing SRD to improve health outcomes, or SRD may be included as one of several determinants of health addressed to improve health outcomes. For both types of intervention approaches, interventions must directly address the cause or source of SRD, not just help individuals or populations to cope with SRD. To this end, it is expected that investigators will collaborate with leadership from organizations, agencies, or programs where the SRD is originating from or being sustained (e.g., a project addressing SRD in the workplace should involve organizational leaders, human resource managers, or other relevant personnel involved in establishing, maintaining, or enforcing workplace policies and practices rather than only involving employees within a workplace). It is also expected that interventions will involve other relevant personnel or individuals within the setting (e.g., teachers, clinicians, co-workers, bystanders) as appropriate to enact changes to SRD, not just those who are directly experiencing SRD.

Research designs should allow for the assessment of mechanisms through which the intervention modifies SRD and how these changes result in improvement in the targeted health outcomes. Mechanisms of interest related to SRD include changes to behaviors, environments, or policies at the interpersonal, organizational, neighborhood/community, or societal level.

Cluster randomized designs for all types of intervention studies are strongly encouraged, as are research designs comparing interventions with and without SRD components. It is expected that the interventions will have potential for sustainability in the intervention setting after the project is over as well as scalability to be implemented in other settings.

Design, Analysis, and Sample Size for Studies to Evaluate Group-Based Interventions: Investigators who wish to evaluate the effect of an intervention on a health-related biomedical or behavioral outcome may propose a study in which (1) groups or clusters are assigned to study arms and individual observations are analyzed to evaluate the effect of the intervention, or (2) participants are assigned individually to study arms but receive at least some of their intervention in a real or virtual group or through a shared facilitator. Such studies may propose a parallel group- or cluster-randomized trial, an individually randomized group-treatment trial, a stepped-wedge design, or a quasi-experimental version of one of these designs. In these studies, special methods may be warranted for analysis and sample size estimation. Applicants should show that their methods are appropriate given their plans for assignment of participants and delivery of interventions. Additional information is available at https://researchmethodsresources.nih.gov/ (https://researchmethodsresources.nih.gov/).

Applicants are strongly encouraged to assess social determinants of health using measures available in the Social Determinants of Health Collection of the PhenX Toolkit (www.phenxtoolkit.org (http://www.phenxtoolkit.org)), as appropriate..

Applications Not Responsive to the FOA

- Projects without a focus on addressing SRD toward one or more NIH-designated populations with health disparities.
- Projects that are exclusively qualitative or that only use individual-level data.
- Projects that do not examine the impact of SRD on health-related outcomes.
- Projects that propose data collection or testing of interventions outside of the U.S.
- Projects that include prohibited policy lobbying or advocacy activities (see https://grants.nih.gov/grants/lobbying_guidance.htm (https://grants.nih.gov/grants/lobbying_guidance.htm) for more information).

Non-responsive applications will not be reviewed. Applicants are strongly encouraged to reach out to the relevant scientific contacts to discuss whether their applications are responsive.

Specific Areas of Research Interest

NIMHD encourages projects that use approaches that encompass multiple domains (e.g., biological, behavioral, socio-cultural, environmental, physical environment, health system) and multiple levels (e.g., individual, interpersonal, community, societal) to understand and address the impact of SRD on minority health and health disparities (see the NIMHD Research Framework, https://www.nimhd.nih.gov/about/overview/research-framework.html (https://www.nimhd.nih.gov/about/overview/research-framework.html), for examples of health determinants of interest).

Areas of specific interest to **NIMHD** include but are not limited to the following:

- Examination of the impact of structural racial/ethnic or socioeconomic status-based discrimination in the criminal justice system (e.g., police stops, arrests, bail and pre-trial detainment and diversion, sentencing, and probation and parole practices) on the health and well-being of individuals, families, and communities.
- Examination of the impact of SRD in health care settings on access to and quality of care and health outcomes.
- Identification of family, organizational, neighborhood, cultural and community protective factors that moderate the relationship between SRD exposures and health.
- Examination of how cumulative and chronic experiences of SRD impact biological processes (e.g., epigenome, allostatic load, inflammation, microbiome, neurological signatures) that contribute to poor health outcomes.
- Examination of the impact of SRD related to social and mass media practices and policies, such as stereotyping, targeted marketing, cyberbullying and hate speech, on community/population-level health.
- Interventions to improve mental and physical health by fostering positive interactions and more inclusive social climates in schools, workplaces, and other organizations/institutions.
- Interventions that address SRD in healthcare settings across multiple domains (clinicians and staff interacting with patients, physical space, service delivery structure, financing, access, and others) in order to improve health care outcomes.
- Place-based interventions to address SRD in multiple sectors (criminal justice, education, labor, transportation, parks and recreation, housing, and others) based on community priorities and strategies.
- Multi-level, multi-component interventions that address SRD as well as other determinants of health to prevent chronic disease, unintentional injury, or violence victimization and perpetration.

NCCIH promotes research on the use of complementary and integrative health approaches for improving minority health and eliminating disparities in health conditions such as mental health, emotional well-being, behavioral health, or pain. Complementary approaches include those with physical and/or psychological therapeutic inputs, often called mind and body approaches (e.g., acupuncture, yoga, tai chi, qi gong, meditation, hypnosis, music therapy, art therapy, spinal or chiropractic manipulation, and massage) as well as approaches with dietary or nutritional therapeutic inputs, or considered natural products (e.g., botanicals, probiotics/microbials, naturally derived peptides, dietary supplements, and special diets). Integrative approaches include therapies that combine complementary approaches with conventional medical interventions such as pharmacologic, surgery, or device-based treatments.

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Areas of interest to **NCCIH** include but are not limited to:

- Studies to examine the impact of SRD on access to, implementation, adherence, dissemination, and adoption of evidence-based complementary and integrative health approaches for prevention and treatment of mental health, emotional well-being, behavioral health, or pain among health disparity populations.
- Multilevel interventions (e.g., interpersonal, community, societal) that address SRD in order to improve access to evidence-based complementary and integrative health approaches to address mental health, emotional well-being, behavioral health, or pain in diverse settings (e.g., schools, criminal justice, health care).

NCI is committed to eliminating cancer related disparities and promoting equity in cancer prevention, diagnosis, treatment, and survivorship. For this FOA, NCI will accept intervention projects focused on addressing structural/institutional racism/discrimination (SRD) that influence cancer-related outcomes -- from early detection through end of life. Projects submitted to NCI may focus on cancer prevention, diagnosis, treatment, and/or survivorship based and provide a conceptual model identifying hypothesized pathways or mechanisms between the SRD and cancer-related outcomes. Areas of specific interest to NCI include multilevel interventions focused on addressing SRD to improve cancer outcomes, or interventions that address several determinants of health in addition to SRD.

NCI areas of interest in intervention research include, but are not limited to:

- Multi-level, multi-component interventions that address SRD as well as other determinants of health to prevent cancer, improve cancer care for patients, and/or improve cancer outcomes.
- Intervention research examining family, organization, neighborhood, cultural and community factors that may moderate SRD exposure and cancer prevention and care.
- Intervention research focusing on the prevention of cancer that incorporates risk and resilience factors in response to structural racism such as historical trauma, immigration policies, school and language-based discrimination, housing and criminal justice practices, etc.
- Research on development of cancer treatment interventions and service delivery approaches that address systemic racism and structural barriers health services such as staff training, service delivery settings and schedules, use of digital platforms, language and health literacy barriers, costs, etc.
- Mechanistic studies of the effects of discrimination-based trauma and/or chronic experiences on biological processes (e.g., epigenome, inflammation, microbiome, or other molecular/cellular processes) that contribute to poorer cancer and overall health outcomes.

NEI will consider applications within our mission areas of preventing, treating, or reversing vision loss and addressing the special health problems and requirements of the visually impaired, with special emphasis on structural racism influences on the delivery of eye health care in underserved populations.

NHGRI is interested in supporting both observational and interventional research that 1) will advance understanding of how SRD intersects with and impacts the field of human genomics, the practice of genomic medicine, and other uses of genomic information that impact health outcomes; or 2) will identify effective strategies for addressing SRD at various levels of influence within and across organizations, institutions, or groups that directly and indirectly contribute to health disparities in genomic medicine. NHGRI defines genomic medicine as use of genomic information in clinical care and the health outcomes associated with that clinical use at an individual, group, and population levels. Areas of specific interest include but are not limited to the following:

1. Examination of the impact of SRD on views, behaviors or experiences of patients and/or providers about the risks and benefits of utilizing genomic information in healthcare to mitigate health disparities.
2. Examination of the role of SRD in whether and how genomic information is used within health care settings (e.g., hospital, health center, private practice) and outside of health care settings (e.g., insurance, labor, criminal justice, direct to consumer genetic testing) and the differential impact of that use on the health and well-being of individuals, families, and communities who experience health disparities.
3. Examination of laws, regulations, policies, guidelines, or interventions that prevent, discourage, or exacerbate racist and discriminatory practices in the use of genomic data, knowledge, and technologies within healthcare settings; and their effectiveness in achieving equity in health outcomes or health service delivery.
4. Interventions that address SRD within healthcare organizations, laboratories, and public health systems to ensure equity in the availability, accessibility, comprehensiveness, and quality of genomic medicine in one or more NIH-designated populations with health disparities in the US.
5. Examination of how SRD biases the design, implementation, and dissemination of genomic research and directly contributes to health disparities in genomic medicine across patient populations (e.g., scientifically valid health-related information, effectiveness of treatment options, evidence-informed care or advice, individual health status), especially for populations whose genetic ancestry is underrepresented in genomic research.

Applicants are encouraged to incorporate the measures from PhenX Toolkit (https://www.phenxtoolkit.org/ (https://www.phenxtoolkit.org/)), whenever possible.

In general, **NHGRI** supports studies that provide generalizable methods and knowledge that can be applied across genomics. Approaches that use a particular disease or organ system as a proof of principle, but can show that methods, outcomes and/or knowledge gained are generalizable, may be in scope for NHGRI. Approaches that are comprehensive across the genome or are generalizable across variants, tissues, diseases, or function also may be in scope for NHGRI.

Applications whose primary scientific objective is to understand a single biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention, will not be in scope for NHGRI. Applications relevant only to a particular disease or organ system should be directed to the appropriate Institute or Center.

Applicants are strongly encouraged to contact the **NHGRI** program directors listed below to discuss the relevance of their proposed topic(s) to the research mission of NHGRI.

The **NHLBI** is interested in the following research topics:

- Observational studies to describe ways in which structural racism and discrimination is associated with disparities in heart, lung, and blood diseases and sleep disorders
- Investigations to uncover the mechanisms by which the multiple domains of structural racism (interpersonal, structural, cultural) impact heart, lung, and blood diseases and sleep disorders
- Hybrid implementation studies to address structural racism to improve heart, lung, and blood diseases and sleep disorders
- Investigations of implementation strategies to increase the uptake of evidence-based strategies to address structural racism
- Community-based research focused on existing practices that support strengths and resilience factors
- Studies to evaluate the impact of structural racism and discrimination in the context of health care settings on heart, lung, and blood diseases and sleep disorders

NIA promotes research related to aging and life course health and well-being, including research on Alzheimer's Disease and related dementias (AD/ADRD). A strategic priority of NIA is understanding the environmental, sociocultural, behavioral and biological drivers of health inequities and disparities related to aging and AD/ADRD. NIA also supports research to develop strategies for the improvement of health among midlife and older adults in racial minority and other populations that experience health inequities/disparities. These priorities are outlined in NIA's strategic directions for health disparities research (https://www.nia.nih.gov/about/aging-strategic-directions-research/goal-health-disparities-adults) and the NAPA Health Disparities milestones (https://www.nia.nih.gov/research/milestones/population-studies-precision-medicine-health-disparities) and reflected within NIA's Health Disparities framework (https://www.nia.nih.gov/research/osp/framework).

NIA encourages investigations of the impacts of the multiple pathways of Structural Racism and Discrimination (SRD) and subsequent health consequences on individuals across the adult lifespan. NIA also encourages research that will investigate how SRD works synergistically with other mechanisms (or forms) of racism (e.g. individual or cultural racism) to influence health outcomes.

Applicants proposing to develop interventions are expected to proactively identify a theory or model that applies to the intervention proposed and the critical variables expected to result in change. Applications are required to use an appropriate experimental design to test the proposed theory, to identify the essential components of complex interventions, or to elucidate the mechanism(s) by which an intervention exerts its effects. For the development of behavioral interventions, applicants are encouraged to articulate their research aims and the stage of intervention development proposed using the NIH Stage Model (https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development) framework.

NIA interests include, but are not limited to, the following:

- Research that examines the mechanisms that produce disparate health and well-being outcomes at older ages due to structural racism including incarceration, segregation, and inequity.
- Investigation of how cumulative and chronic experiences of SRD impact mechanisms related to premature aging or increased risk for AD/ADRD.
- Studies of structural or institutional factors that mitigate or exacerbate disparities in access to healthcare services in midlife and older age adults or healthcare services for AD/ADRD patients and their caregivers.
- Studies to elucidate whether and how mechanisms connecting structural racism to aging- relevant health outcomes, including well-being, independent function, cognition and AD/ADRD, operate on multiple levels (e.g., individual, interpersonal, societal).
- Multi-level, multi-component interventions that address SRD in healthcare settings to improve aging outcomes, prevent premature aging or AD/ADRD, and/or improve care for older adults, including those with AD/ADR.

NIAAA is interested in prevention, health services and treatment interventions that address the impact of structural racism and discrimination on the development, course and recovery from alcohol misuse and alcohol use disorders. While observational research might be part of formative work necessary to develop effective interventions, the focus of the proposed research ***must*** be on interventions to address alcohol problem. Areas of interest to NIAAA include but are not limited to:

- Research on prevention of early initiation of and/or continued alcohol use across the lifespan that incorporates risk and resilience factors in response to structural racism such as historical trauma, immigration policies, school and language-based discrimination, housing and criminal justice practices, etc.
- Research on development of treatment interventions and service delivery approaches that address systemic racism and structural barriers to alcohol use services such as staff training, service delivery settings and schedules, use of digital platforms, language and health literacy barriers, costs, etc.
- Integration of culturally-grounded, culturally competent and/or bilingual alcohol prevention and treatment services that address effects of structural racism in general health and specialty services settings (including aftercare), school based settings, criminal justice settings, etc.

NIAID supports basic and applied research to better understand, treat, and prevent infectious, immunologic, and allergic diseases, with the goal of developing new therapies, vaccines, diagnostic tests, and other technologies. Research areas include microbiology and infectious diseases, HIV/AIDS and HIV/AIDS-related research, immunology, allergy, transplantation, and biodefense. NIAID is interested in intervention research within the scope of NIAID's mission that will develop and evaluate strategies that mitigate the impact of structural racism and discrimination (SRD).

Specific areas of interest to **NIAID** include, but are not limited to:

HIV/AIDS Research

- Strategies to identify and end structural racism in health care settings of relevance to persons with HIV (PWH) including structural racism that may impact the type of care that is offered to PWH, the way the care is delivered, and racism existent in care adjacent settings that may impact PWH.
- Strategies to identify and end structural racism in non-care settings that may impact the ability of PWH to engage in appropriate medical care and/or fully benefit from medical care.
- Research to address SRD at the health policy, organization and provider levels that fosters medical mistrust and impedes uptake and retention in HIV prevention and treatment programs.
- Research to identify and counter SRD and related intersectional stigma resulting from the impact of HIV, sexual/gender affiliation and/or common co-occurring medical and social conditions (e.g., mental health and substance abuse disorders, poverty).
- Characterization of targeted interventions that can be deployed as public health policies to mitigate the impact of SRD that exists in health systems and health care delivery strategies to improve engagement and retention in care among populations affected by SRD.
- Research to elucidate effective patterns of communications that enable healthcare providers of all races and ethnicities to overcome barriers of medical mistrust in healthcare and improve participation of racial minorities in research.
- Research to evaluate structural interventions that address disparities in access to research by both participants and researchers from racial and ethnic minorities; and, the role of racism and health disparities in terms of access to both accurate HIV prevention information and pre-exposure prophylaxis (PrEP) products, including the continued and consistent use of HIV PrEP.

Allergy, Immunology and Transplantation

- Role of SRD in sustaining disparities in the development, prevalence, and management of asthma, food allergies, allergic rhinitis, allocation of organs for transplantations, allograft function and survival in children from low-income families and racial and ethnic minorities.
- Examine the contribution of SRD to 1) the morbidity and mortality and 2) the hesitancy to participate in clinical research and methods to overcome the hesitancy, seen in some autoimmune diseases (e.g. Systemic lupus erythematosus (SLE) that are more common and potentially more severe in racial and ethnic minorities.
- Interventions to evaluate the impact of SRD on access to kidney transplantation among persons on renal dialysis.

Infectious Diseases

- Research that studies the impact of SRD on infectious disease (ID) prevalence and health outcomes, access to ID vaccines, diagnosis, prevention technologies and products, and treatment along with service delivery models to expand access and utilization in racial, ethnic, and sexual minorities.
- Effects of SRD on health outcome following respiratory and sexually transmitted diseases (e.g. COVID-19, gonorrhea, syphilis), vaccine uptake (e.g. COVID-19, HPV) and access to diagnosis and treatment especially Sexually Transmitted Infections (STIs).
- Innovative treatment options to address antimicrobial resistance (especially STIs and Tuberculosis (TB), supply chain limitations, and other barriers to effective treatment.

NIAMS encourages research designed to understand and address the impact of SRD on minority health and health disparities, among underserved and minority populations who are also at risk for or who are patients with NIAMS diseases of interest (arthritis, musculoskeletal, skin). NIAMS has interest in research understanding and addressing macro-level factors that underlie SRD and subsequent health consequences.

Areas of specific interest to **NIAMS** under this RFA include but are not limited to:

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Observational research with focus on:

- Examination of the impact of SRD on access to and quality of care, including delays in diagnoses, treatment and rehabilitation.
- Identifying protective factors at multiple upstream levels (family, organizational, neighborhood, cultural and community) that are associated with less impact of SRD on health outcomes.
- Utilization of innovative design and analysis methods to evaluate natural experiments of existing efforts to mitigate SRD at a macro-level.

Intervention research with focus on:

- Projects that focus on prevention interventions that can reduce SRD and improve health-outcomes in NIAMS mission-relevant diseases.
- Projects that use multi-level and multi-component interventions that address SRD to improve health-outcomes in arthritis, musculoskeletal, and skin diseases.

NIBIB supports the development and integration of advanced bioengineering, sensing, imaging, and computational technologies for the improvement of human health and medical care.

Areas of specific interest to **NIBIB** under this FOA include. but are not limited to the following:

- Observational research to understand the role of structural racism and discrimination in causing and sustaining health disparities mediated through biomedical technologies (e.g., biomedical imaging, bioinformatics and bioengineering), such as
    a. the exclusion or inappropriate consideration of racial differences in needs finding, specification, design and testing of these technologies.
    b. the lack of availability, access, or insufficient/inappropriate application of such technologies in the prevention, diagnosis, and treatment of disease for certain groups or in certain settings, and
- Intervention research that addresses

    a. the eradication of implicit bias and racism in approaches and assumptions in needs finding, specification, design and testing of biomedical technologies,
    b. improving minority health, promoting health equity, and eliminating health disparities through the innovation of novel technologies or enhancement of existing technologies in biomedical imaging, bioinformatics and bioengineering.

NIBIB funding of clinical trials will be in accordance with NOT-EB-21-005 "NIBIB Guidance for Support of Clinical Trial Applications." Briefly, NIBIB will only support mission-focused (see NIBIB's program areas) early-stage clinical trial applications, i.e., feasibility, Phase I, first-in-human, safety, or other small clinical trials, that inform early-stage technology development. NIBIB will not support applications proposing pivotal, Phase II, III, IV, or trials in which the primary outcome is efficacy, effectiveness, or a post-market concern. Also, mechanistic trials are not supported unless the primary focus of the project is on technology development.

NICHD seeks applications that will address questions relevant to the NICHD mission and should align with the NICHD Strategic Plan (https://www.nichd.nih.gov/about/org/strategicplan).

NICHD is interested in the following **populations**: Infants, children, adolescents, and individuals in the transition from adolescence to adulthood; pregnant and lactating women; men and women of reproductive age with regards to reproductive health; girls and women from pre-puberty through perimenopause with regards to research on gynecological and/or reproductive health; individuals of any age with intellectual delays and/or disabilities. NICHD is also interested in research on how parents and other caretakers and/or family members exposure to SRD affects health outcomes for the NICHD populations of interest. In addition, NICHD is interested in research on how prospectively measured exposures to SRD in childhood affects adult health outcomes. NICHD is interested in both observational and intervention research, and, among observational research projects using longitudinal designs, is particularly interested in use of population-representative data.

NICHD is interested in the following **health and health-related outcomes**: Maternal and infant mortality and morbidity, adolescent and young adult mortality and morbidity; contraceptive use and non-use; reproductive health, gynecological health, and fertility; and, for NICHD populations of interest, access to health care and diagnosis and treatment of health problems. NICHD is interested in research on all the **domains** in which SRD may occur that are listed in this RFA, with particular interest in educational settings; the criminal justice system, including the juvenile justice system; and gynecological/reproductive health settings. NICHD is also interested in research on SRD that affects exposure to violence among NICHD populations of interest.

The **National Center for Medical Rehabilitation Research** within **NICHD** seeks applications for intervention research on individuals with physical disabilities. Areas of interest include but are not limited to referrals for and access to health care and inpatient and outpatient rehabilitation services for both primary and secondary conditions, and outcomes related to improving functional outcomes.

NIDA is interested in supporting observational/etiologic, prevention, treatment, and health services research to address the impact of structural racism and discrimination on substance use, substance use disorders, substance use consequences, and comorbid conditions including HIV. Topics of interest include but are not limited to:

- Research on the extent to which racial discrimination, systematic inequities, and segregation in housing, education, employment opportunities, and health resources contribute to and perpetuate disparities in access to substance use and HIV prevention, addiction treatment, and recovery services.
- Research on the effects of systematic racism and discrimination on behavioral, cognitive, and neurobiological markers known to increase vulnerability to substance use, substance use disorders, and HIV across the lifecourse.
- Studies of how bias in the criminal justice system, including arrest, incarceration, probation and post-sentencing practices, affect substance use trajectories, HIV/HCV risk, addiction-related health outcomes, and health disparities experienced by communities of color.
- Targeted efficacious, effective and scalable, culturally specific interventions to address social determinants of health by promoting resiliency and confronting structural racism, with a focus on stigma, discrimination, and prejudice in the context of SUD and HIV prevention and treatment services.
- Research partnerships with state and local officials to determine the impact of administrative and legislative measures to improve equity within housing, education, employment, and other areas of public policy on substance use outcomes in youth and adolescents.
- Research partnerships with state/local agencies and private or public health systems to develop models to eliminate systemic barriers to addiction care or addiction and HIV care, particularly those rooted in racism or structural discrimination.

NIDCD encourages either observational or interventional projects that aim to better understand and address the impact of SRD on minority health and health disparities as they relate to the mission areas of hearing, balance, taste, smell, voice, speech, and language across the lifespan. Areas of interest include but are not limited to applications that address the influence and mitigation of SRD on:

- the diagnosis, treatment, and re/habilitation of childhood hearing, voice, speech, and language disorders.
- the diagnosis, treatment, and rehabilitation of adults with communication disorders including but not limited to hearing loss and acquired neurologic communication disorders.
- the development and interpretation of tests/assessment approaches for voice, speech and language disorders and differences, including measures of dialectal code switching.

NIDCR is interested in observational research aimed at understanding the role of structural racism and discrimination (SRD) in contributing to oral health disparities. Additionally, interventional research that addresses SRD, with the goal of improving minority oral health and reduce oral health disparities, is of interest through this FOA.

Areas of specific interest to **NIDCR** include, but are not limited to, the following:

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- Examination of racial/ethnic differences in management and treatment approaches for dental, oral, and craniofacial diseases/conditions, and the role of multi-level SRD factors (e.g. policies, organization characteristics, provider unconscious/implicit bias, etc.) in contributing to these differences.
- Examination of the impact of SRD on access to and quality of care and oral health outcomes, including the role residential segregation may play.
- Examination of the role of language barriers, cultural differences between patients and dental providers, or other impacts of multi-level SRD that may prevent minority groups from seeking oral health care.
- Identification of family, organizational, neighborhood, cultural, and community protective factors that moderate the relationship between SRD exposures and oral health.
- Interventions that address SRD in settings where oral health care is delivered across multiple domains (e.g. provider-patient interactions, service delivery, access to care, etc.) to improve oral health outcomes in minority groups that experience a higher prevalence of oral disease than their counterparts.

NIDDK is committed to promoting health equity and reducing and eliminating health disparities relevant to diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases. For this FOA, NIDDK is interested in intervention projects focused on understanding and addressing the impact of structural racism and discrimination (SRD) on patients and populations disproportionately affected by conditions that fall within the mission of NIDDK. Meaningful stakeholder engaged approaches are encouraged to improve feasibility and maximum potential for sustainability of successful interventions beyond the funded project period. NIDDK is also interested in observational studies, such as deep characterization of SRD that will inform interventional studies and evaluation of natural experiments that employ appropriate designs and methodologies necessary to strengthen causal inferences.

NIDDK will not support studies that focus solely on training health care providers or testing communication and dissemination strategies to facilitate the use of health information.

The mission of **NIEHS** is to discover how the environment affects people to promote healthier lives. The NIEHS 2018-2023 Strategic Plan (https://www.niehs.nih.gov/about/strategicplan/index.cfm) emphasizes our ongoing commitment to the study of environmental health disparities and need for environmental justice among communities affected by toxic levels of exposure. Importantly, structural factors contribute to disproportionate exposure burdens affecting the health of racial, ethnic, immigrant, socioeconomically disadvantaged, and rural communities. Structural factors that intersect with environmental health include, for example, reversal of environmental protections that regulate harmful pollutants, and redlining practices or residential segregation that result in the location of racial/ethnic communities near industrial and/or heavily polluted areas.

NIEHS is interested in observational research examining the role of structural racism and discrimination (SRD) as a significant determinant in environmental health disparities, or evidence-based intervention research that mitigates or prevents the negative health outcomes attributable to environmental SRD. Applicants are ***strongly encouraged*** to utilize community engaged research approaches and include letters of support from community partners. Applications that demonstrate collaborative (i.e., community-academic partnerships) approaches to understand and/or address the negative health effects of environmental SRD across ***multiple*** health disparity communities will be prioritized. Areas of specific interest to NIEHS in environmental SRD include, but are not limited to: single or combined environmental exposures (i.e., mixtures) affecting the health of communities; health impacts of climate change, extreme weather and natural or human caused disasters; the built environment and greenspace, including green gentrification; studies grounded in community identified concerns around the intersection of environmental SRD and health outcomes; the impact of environmental SRD on health outcomes across the lifespan; and the role of environmental SRD in occupational exposures.

NIGMS supports basic research that increases our understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS' research mission (https://www.nigms.nih.gov/about/overview/) is aimed at understanding the principles, mechanisms, and processes that underlie living organisms, often using research models. NIGMS does not support research that is relevant to the diseases, organ systems, stages of life, or populations within the mission areas of other NIH Institutes and Centers. Areas of interest to NIGMS include but are not limited to studies that address:

- The impact of structural racism and discrimination (SRD) on health disparities that affect conditions related to clinical areas that NIGMS supports: sepsis (see NOT-GM-19-054 (NOT-GM-19-054)), injury and critical illness, anesthesiology, clinical pharmacology, wound healing, and innate immunity and inflammation.
- The sources of bias in computational research using electronic health records and other health-related data (e.g., artificial intelligence, machine learning, and development of improved algorithms and other methodologies), and/or the development of effective strategies to reduce these disparities.
- Computational modeling to understand the sources of SRD on health disparities in infectious disease spread, and/or to develop effective strategies to reduce these disparities.
- Mechanistic studies of the effects of discrimination-based social trauma on epigenetic and other molecular or cellular processes.

NIMH is interested in receiving applications that address research priority areas in translational, services and interventions research focused on mental health outcomes; and applications that address NIMH priority areas in HIV/AIDS research. Areas of interest include, but are not limited to, those below.

Translational Research:

- Elucidate mechanisms at the individual, community, and organizational levels by which structural racism and discrimination result in specific adverse mental health outcomes across the lifespan, especially those that can point towards therapeutic targets.
- Identify how structural racism and discrimination impact trajectories of mental health disorders across the lifespan, particularly focusing on sequential and integrative relationships across neural, behavioral, and environmental factors that lead to disparities in mental health outcomes.
- Studies that use or develop methods to systematically and reliably quantify individual exposure to structural racism and discrimination, including development of rigorous measures of environmental and sociocultural factors like neighborhood effects, access to and quality of healthcare, food and resource security, intersectionality, and cultural beliefs.

Interventions Research:

NIMH is interested in applications that focus on mental health as the primary outcome. Intervention research may include mental health promotion, prevention and/or treatment Interventions. Interventions may focus primarily on addressing structural racism and discrimination to improve mental health outcomes. Consistent with NIMH's experimental therapeutics approach, research designs should allow for the assessment of mechanisms through which the intervention modifies structural racism and discrimination and how these changes result in improvement in the targeted mental health outcomes. See the Support for Clinical Trials at NIMH (https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml)web page for additional information regarding dedicated FOAs for NIMH clinical trials research support.

Areas of interest include, but are not limited to:

- Interventions to address structural racism and discrimination by cultivating positive interactions and inclusive climates in schools, workplaces and other institutions, with the goal of improving mental health.
- Interventions to improve mental health and associated comorbidities by addressing structural racism and discrimination that takes place in different institutional settings (e.g., child welfare, juvenile and criminal justice, education, housing, etc.).
- Interventions to address structural racism and discrimination at the community level, with the goal of reducing risk for mental health and associated difficulties.

Services Research:

- Non-intervention studies to identify specific, mutable factors indicative of structural racism and discrimination that may serve as targets of interventions to reduce structural racism as it impacts mental health outcomes.
- Non-intervention studies designed to examine structural factors that might be used to identify and/or measure systematic health disparities (e.g., use E.H.R. to examine patient, provider, and system level factors that represent systematic differences in identification, referral, quality of care).
- Studies testing the effectiveness of provider-, organization-, or systems-level interventions in reducing or eliminating structural racism and testing whether such reductions mediate improved mental health outcomes.
- Studies identifying structural aspects of provider, clinic, organization or systems processes in specific systems (e.g.: school or school systems, health care systems, justice systems, etc.) that may be associated with mental health outcomes and may serve as indicators of and measures of changes in structural racism.

HIV/AIDS Research:

- Studies to identify and address the mechanisms, pathways and negative impact of structural racism, discrimination, and intersectional stigma on HIV outcomes across the prevention, care and treatment continuum.
- Studies that examine the impact of bias and discrimination on patient-provider communication, informed decision-making, and HIV care outcomes in service delivery settings.
- Research to understand the role of structural racism and discrimination on uptake of HIV testing, PrEP and other biomedical prevention strategies on individuals from high-incidence populations.
- Research to explore strengths-based approaches, mechanisms for change and opportunities for trust-building and engagement in communities that have been historically impacted by racism and discrimination and are also disproportionately impacted by HIV.
- Studies to identify societal factors that contribute to persistent discrimination, polices or laws associated with HIV vulnerabilities or resiliencies (positive outcomes) over time.
- Studies to identify ways to combat HIV misinformation and poorly delivered communication that contributes to racism, xenophobia and other discriminatory practices that negatively impact HIV outcomes.

NINDS commits to reducing the disproportionate burden of neurological diseases experienced by underserved groups of society, including racial and ethnic minoritized, rural, and socioeconomically disadvantaged populations, by funding a spectrum of research from basic science through clinical studies and training the next generation of health equity investigators (https://www.ninds.nih.gov/Current-Research/Focus-Tools-Topics/Health-Disparities). NINDS supports research activities focused on understanding how structural racism and discrimination (SRD) contribute to inequalities in neurologic health, healthcare, and health outcomes in disparate populations, including racial and ethnic minorities, the geographically disadvantaged, sexual and gender minoritized individuals and others who have been historically underserved, marginalized, and adversely affected by persistent inequality and socioeconomic disadvantage.

NINDS is particularly interested in:

- Research on the impact of SRD on mechanisms related to increased risk of cognitive impairment and Alzheimer's Disease Related Dementias (Frontotemporal degeneration, Lewy Body dementia, mixed etiology dementias and vascular contributions to cognitive impairment and dementia).
- Research on structural or institutional factors that mitigate or exacerbate neurological inequalities in access to healthcare services for midlife and older age adults and/or ADRD patients and their caregivers/families.
- Studies to elucidate whether and how mechanisms connecting structural racism to neurological health outcomes, including well-being, independent function, cognition and ADRD, operate on multiple levels (e.g., individual, interpersonal, or societal).

A letter of intent and communication with **NINDS** program staff prior to submission of an application is strongly encouraged. Observational studies should be theory-based to enable the future development of actionable items and evidence-based interventions. Applicants proposing to develop interventions are expected to proactively identify a theory or model that applies to the intervention proposed and the critical variables expected to result in change. Applications are required to use an appropriate experimental design to test the proposed theory, identify the essential components of complex interventions, and/or elucidate the mechanism(s) by which an intervention exerts its effects. For the development of behavioral interventions, applicants are encouraged to articulate their research aims and a proposed framework.

NINR supports research that uses nursing's holistic perspective to improve individual and population health outcomes and eliminate health inequities by bridging biomedical science and provision of healthcare services with the realities of people's lives and living conditions (i.e., social determinants) across the clinical and community settings where nurses practice. These settings include hospitals, clinics, people's homes, long-term care facilities, schools, workplaces, criminal justice facilities, and the community at large. NINR recognizes the importance of engaging with and responding to the experiences of individuals, households, and populations.

Areas of specific interest to **NINR** include but are not limited to the following topics:

- Developmental, evaluation, and implementation research concerning interventions, programs, and policies aimed at addressing structural discrimination across clinical and community settings for their health effects. Studies adopting natural experiment, and clinical trial designs are all of interest, especially those adopting a holistic perspective on individual and population health.
- Studies aimed at better understanding factors moderating negative health effects of SRD. Studies of innovative models of care including social care and trauma-informed care are encouraged.
- Research on system level interventions to reduce negative effects of implicit bias in healthcare providers on health outcomes for NIH-designated populations with health disparities.

NINR will not support studies that focus solely on training nurses or other healthcare providers to reduce SRD.

The **OBSSR** is part of the Office of the Director of NIH and works in partnership with the 27 NIH Institutes and Centers to ensure that behavioral and social sciences research is well integrated into the NIH research enterprise. In alignment with its strategic priorities (https://obssr.od.nih.gov/about/strategic-plan/), **OBSSR** is interested in providing co-funding support for project(s) funded under this RFA that do one or more of the following: incorporate novel ways of assessing SRD; focus on the mechanisms through which SRD influence health outcomes; incorporate implementation science approaches; utilize innovative methods to evaluate natural experiments of existing efforts; identify protective factors and resiliency-based approaches. Note that OBSSR does not accept assignment of applications or manage awards that are funded. Please contact one of the ICs for inquiries regarding the suitability of the proposed project for the RFA and the IC's research portfolio.

The **ODP** is the lead office at the NIH responsible for assessing, facilitating, and stimulating research in disease prevention, and disseminating the results of this research to improve public health. In partnership with the 27 NIH Institutes and Centers, ODP strives to increase the scope, quality, dissemination, and impact of NIH-supported prevention research. The ODP is interested in providing co-funding support for projects that have strong implications for disease prevention, promise for wide uptake, and that include innovative and appropriate design, measurement, and analysis methods. ODP has specific interests in projects seeking to do one or more of the following: develop analytic methods for rigorously measuring the structures and systems that sustain racial inequities; develop or adopt data sources and methods that accurately and appropriately represent minority and vulnerable communities; capitalize on community-based participatory research approaches for developing and testing interventions; assess for race/ethnic differences; incorporate implementation science approaches and strategies that will be responsive to community and health/service system needs; utilize innovative methods to evaluate natural experiments in healthcare and services delivery and health promotion interventions; and, increase uptake and long-term sustainability of evidence-based interventions and approaches. For additional information about ODP's research priorities and interests, please refer to the **ODP Strategic Plan for Fiscal Years 2019 2023** (https://prevention.nih.gov/about-odp/strategic-plan-2019-2023).

Applications must be relevant to the objectives of at least one of the participating NIH Institutes and Centers (IC) listed above. ODP does not award grants. Please contact the relevant IC Scientific/Research Contact(s) listed below for questions regarding IC research priorities and funding.

The **ORWH** is part of the Office of the Director of NIH and works in partnership with the 27 NIH Institutes and Centers to ensure that women's health research is part of the scientific framework at the NIH and is supported in the larger scientific community. Research in recent decades has adopted an intersectionality framework to study and explain the complex nature of inequality. Integrating the purposeful accounting of sex as a biological variable (SABV) and gender as a social variable, alongside race and social class considerations in biomedical research, will enhance understanding of the effects of discrimination and its magnitude on mental and physical health (i.e. impacts on maternal morbidity and mortality or multimorbidities among groups of women). **ORWH** is interested in providing support for interdisciplinary, behavioral, clinical, and/or translational studies incorporating intersectional analyses into studies of racism and discrimination exposure among populations experiencing health disparities, including groups of women who are understudied, underrepresented, and underreported in research. For additional guidance, please refer to the 2019-2023 Trans-NIH Strategic Plan for the Health of Women on the ORWH website (https://www.nih.gov/women/strategicplan (https://www.nih.gov/women/strategicplan)).

The **SGMRO** resides in the NIH Office of the Director and coordinates research and activities related to the health of sexual and gender minorities (SGMs; see NOT-OD-19-139 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-139.html) for more information) by working directly with the agency's Institutes, Centers, and Offices. A robust and growing body of evidence demonstrates that SGMs often face institutional discrimination and poorer health outcomes than their non-SGM peers. SGM people with intersecting identities, including those based on race, ethnicity, and/or other statuses highlighted in this FOA, may face distinct and exacerbated health issues and disparities, and structural racism and discrimination may act as key drivers, modifiers, and intensifiers of the health-related concerns and challenges of these individuals. **SGMRO** is interested in social, behavioral, clinical, translational, and health services research to investigate how structural racism and discrimination adversely affect the lives and well-being of the most vulnerable SGM populations and to develop sustainable long-term strategies to attend to these pressing issues.
See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s).

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

NIMHD intends to commit $5,000,000 in FY2022 to fund 6-7 awards.

NCI intends to commit $1,000,000 in FY2022 to fund one award.

NCCIH intends to commit $850,000 in FY2022 to fund one award.

NEI intends to commit $1,000,000 in FY2022 to support one award.

NHGRI intends to commit $1,700,000 in FY2022 to fund 2 awards.

NHLBI intends to commit $1.5M to support up to 2 awards.

NIA intends to commit $4,500,000 in FY2022 to fund 6 awards, including $3,000,000 to fund 4 awards on Alzheimer's disease and related dementias and $1,500,000 to fund 2 awards on other topics.

NIAAA intends to commit $850,000 in FY2022 to fund one award.

NIDDK intends to commit $850,000 in FY 2022 to fund one award.

NIAID intends to commit $850,000 in FY2022 to fund one award.

NIAMS intends to commit $500,000 in FY2022 to fund one award.

NIBIB intends to commit $800,000 in FY2022 to fund one award.

NICHD intends to commit $850,000 in FY2022 to fund one award.

NIDA intends to commit $2,000,000 in FY2022 to fund 2 awards.

NIDCD intends to commit $700,000 in FY2022 to fund one award.

NIDCR intends to commit $750,000 in FY2022 to fund one award.

NIEHS intends to commit $850,000 in FY2022 to fund one award.

NIGMS intends to commit $2,000,000 in FY2022 to fund 4-6 awards.

NIMH intends to commit $850,000 in FY2022 to fund one award.

NINDS intends to commit $850,000 in FY2022 to fund one award.

NINR intends to commit $2,550,000 in FY2022 to fund 3 awards.

The OD, OBSSR, ODP, ORWH, and SGMRO have committed funds in FY2022 towards co-funding.

Award Budget

Application budgets are limited to $500,000 direct costs annually, not including consortia F&A.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments

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- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are not** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html))

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Yujing Liu, MD, PhD
National Institute on Minority Health and Health Disparities (NIMHD)
Telephone: 301-827-7815
Email: liuyujin@mail.nih.gov

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy: Identify the health disparity populations that will be the focus of the project and describe the documented health disparity that will be studied. Provide a justification for how the specific types of SRD to be studied constitute SRD. Provide a conceptual model that describes hypothesized causal pathways between SRD and health outcomes. Describe data sources that will be used to document SRD. Provide a data analytic plan that specifies how multi-level factors, intervention effects and interactions, or outcomes will be handled, as appropriate. Describe and specify the roles of collaborators. For intervention projects, describe how the intervention will directly address the cause or source of SRD. Specify how organizations, agencies, or programs where the SRD is originating from or being sustained will be involved in the project, including involvement of leadership from these organizations as well as other individuals or groups. Describe the potential of the intervention to be sustainable in the intervention settings after the project is over and scalable to other settings.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered Yes to the question Are Human Subjects Involved? on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

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Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this FOA: Does this project identify clearly and provide justification for study of the targeted health disparity populations? Does the project address a documented health disparity that is clearly specified and justified? Is an appropriate justification provided for how the types of SRD to be studied constitute SRD? Is an appropriate conceptual model provided that describes hypothesized causal pathways between SRD and health outcomes? For intervention projects, is a clear and compelling rationale provided for how the intervention will directly address the cause or source of SRD? Does the intervention have potential to be sustainable in the intervention settings after the project is over and scalable to other settings?

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA: Are the roles of collaborators clearly described and appropriate? For intervention studies, is the involvement of personnel from the organizations, agencies, or programs where the SRD is originating from or being sustained specified and appropriate?

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Specific to this FOA: Are the data sources used to document SRD identified and appropriate? Is an appropriate data analytic plan provided that specifies how multi-level factors, intervention effects and interactions, or outcomes will be handled, as applicable?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of

procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition, for applications involving clinical trials

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (//grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Not Applicable.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan (GDS) (//grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NIMHD, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Appeals (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Representation of health disparity populations and/or types of SRD addressed.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.
Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain applicable clinical trials on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov (https://register.clinicaltrials.gov/)). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm (https://grants.nih.gov/policy/clinical-trials/reporting/index.htm)

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (https://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html).

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov). For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html); https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf (https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161)
A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 Award Term and Conditions for Recipient Integrity and Performance Matters.

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Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
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E-mail: bucheimera@mail.nih.gov (mailto:bucheimera@mail.nih.gov)

Tamara Kees
National Institute of Mental Health (NIMH)
Telephone: 301-443-8811
Email: tamara.kees@nih.gov (mailto:tamara.kees@nih.gov)
Jenny L Greer
National Institute Of Environmental Health Sciences (NIEHS)
Phone: 984-287-3332
E-mail: jenny.greer@nih.go (mailto: jenny.greer@nih.gov)

Ron Wertz
National Institute of Nursing Research (NINR)
Telephone: 301-594-2807
Email: wertzr@mail.nih.gov (mailto:wertzr@mail.nih.gov)

Bryan S. Clark, MBA
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
Telephone: 301-435-6975
Email: clarkb1@mail.nih.gov (mailto:clarkb1@mail.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?03-26-21)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

National Institutes of Health (/grants/oer.htm)
Office of Extramural Research

(https://www.hhs.gov/) Department of Health and Human Services (HHS)

USA.gov (https://www.usa.gov/)

NIH... Turning Discovery Into Health®

EXHIBIT C

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:28 AM
To: Takade, Tiffany <Tiffany.Takade@ucsf.edu>
Subject: Grant Termination Notification

This Message Is From an External Sender

This message came from outside your organization.

National Institutes of Health
Office of Extramural Research

3/21/2025

Takade, Tiffany
University Of California, San Francisco
tiffany.takade@ucsf.edu

Dear Takade, Tiffany:

Effective with the date of this letter, funding for Project Number 5R01AG077934-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 6/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Jeni Militano (Acting), Chief Grants Management Officer, NIA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT D

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG077934
Federal Award Date
03/24/2025

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, THE
1855 FOLSOM ST STE 425
SAN FRANCISCO, CA 94103

2. Congressional District of Recipient
11

3. Payment System Identifier (ID)
1946036493A6

4. Employer Identification Number (EIN)
946036493

5. Data Universal Numbering System (DUNS)
094878337

'. Recipient's Uni7ue Entity Identifier
KMH5K9V7S518

6. Project Director or Principal Investigator
Jesus Ramirez-Valles, PHD
Professor And Director
jesus.ramirez-valles@ucsf.edu
3129721409

8. Authorized Official
Tiffany Takade
tiffany.takade@ucsf.edu
415-987-1546

Federal Agency Information

9. Awarding Agency Contact Information
Morgan Amanda Granetz

NATIONAL INSTITUTE ON AGING
morgan.granetz@nih.gov

10. Program Official Contact Information
Melissa S Gerald
Health Science Administrator
NATIONAL INSTITUTE ON AGING
geraldmel@nia.nih.gov
301-402-4156

Federal Award Information

11. Award Number
5R01AG077934-03

12. Uni7ue Federal Award Identification Number (FAIN)
R01AG077934

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Structural Racism and Discrimination in Older Men's Health Inequities

15. Assistance Listing Number
93.866

1'. Assistance Listing Program Title
Aging Research

16. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 06/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$800,878
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$800,878
2'. Project Period Start Date 09/15/2022 **– End Date** 03/21/2025	
26. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,554,402

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Philip E. Smith

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 5R01AG066934-03 RE: ISED

Principal Investigator(s)Y
Jesus Ramirez-Valles, PHD

Award e-mailed toYcgrasteam@ucsf.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Regents of the UCSF in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG077934. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Philip E. Smith
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$273,776
Fringe Benefits	$105,332

A1195

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Personnel Costs (Subtotal)	$379,108
Materials & Supplies	$480
Travel	$20,558
Other	$50,150
Subawards$Consortium$Contractual Costs	$69,146
Publication Costs	$2,789
Federal Direct Costs	$522,231
Federal F&A Costs	$278,647
Approved Budget	$800,878
Total Amount of Federal Funds Authorized (Federal Share)	$800,878
TOTAL FEDERAL AWARD AMOUNT	$800,878
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARV TOTAL FEDERAL AWARD AMOUNT VEAR (3) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
5R01AG077934-03	$800,878
3R01AG077934-03S1	$101,549
TOTAL	**/ 902,426**

SUMMARV TOTALS FOR ALL VEARS (for this Document Number)		
VR	**THIS AWARD**	**CUMULATI: E TOTALS**
3	$800,878	$902,427

Fiscal InformationY

Payment System IdentifierY	1946036493A6
Document NumberY	RAG077934A
PMS Account TypeY	P (Subaccount)
Fiscal VearY	2024

IC	CAN	2024
AG	8470694	$800,878

NIH Administrative DataY
PCC: 2BPDIGE / **OC**: 41025 / **Released**: 03/21/2025
Award ProcessedY03/24/2025 12:04:40 AM

SECTION II – PAVMENT$HOTLINE INFORMATION – 5R01AG066934-03 RE: ISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AG066934-03 RE: ISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D)Y All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG077934. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data*

reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program IncomeY
Additional Costs

SECTION I: – AG SPECIFIC AWARD CONDITIONS – 5R01AG066934-03 RE: ISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

It is the policy of NIH not to prioritize DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to

expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.. Therefore, this project is terminated. UNIVERSITY OF CALIFORNIA-SAN FRANCISCO may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Supersedes Notice of Award issued 06/12/2024. Previous terms and conditions apply:

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

This award includes funds awarded for consortium activity with SAN FRANCISCO STATE UNIVERSITY. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

This award includes funds awarded for consortium activity with University of Alabama at Birmingham. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement Page 6 of 6 Version: 13 - 8/3/2022 12:59 PM | Generated on: 5/12/2023 12:19 AM is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

This award includes funds awarded for consortium activity with University of Tulane Univ. School of Public Health and Tropical Medicine. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

SPREADSHEET SUMMARV
AWARD NUMBERY5R01AG077934-03 REVISED

INSTITUTIONYThe Regents of the UCSF

Budget	Year 3
Salaries and Wages	$273,776
Fringe Benefits	$105,332
Personnel Costs (Subtotal)	$379,108
Materials & Supplies	$480
Travel	$20,558
Other	$50,150
Subawards/Consortium/Contractual Costs	$69,146
Publication Costs	$2,789
TOTAL FEDERAL DC	$522,231
TOTAL FEDERAL F&A	$278,647
TOTAL COST	$800,878

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	61.5%
F&A Cost Base 1	$453,085
F&A Costs 1	$278,647

EXHIBIT E

March 12, 2025

Drexel University
Susan Elkins
DUResearch@drexel.edu

Dear Susan Elkins:

Funding for Project Number 1R01MD020284-01 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on August 22, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5 1R01MD020284-01is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.12 16:59:58 -04'00'

Michelle G. Bulls, ***on behalf*** of Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Administration
Office of Extramural Research

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[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF APHA MEMBER 10

I, Annelise Mennicke, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. I am an Associate Professor at the University of North Carolina, Charlotte School of Social Work.

2. I am offering this declaration in my individual capacity and not on behalf of my employer.

3. I received my Doctor of Philosophy and Master of Social Work from Florida State University in 2015 and 2011, respectively, and my Bachelor of Science in Psychology from the University of Florida in 2008.

4. My research is primarily centered on violence prevention, with an emphasis on sexual assault on college campuses. My current work aims to develop strategies that mitigate interpersonal violence, support survivors of sexual assault, and evolve effective prevention methods.

5. My dedication to this field originates not only from my three years of firsthand experiences as a volunteer victim's advocate at a rape crisis center in Florida but also from a deeply personal place—my father was murdered. This life-altering loss instilled in me a profound understanding of the devastating impact of violence. Having both personal and professional experience observing the lasting impacts of violence on individuals solidified my commitment to finding and

implementing evidence-based solutions to best support the healing process of survivors and reduce the chances of revictimization.

6. I have authored or co-authored over seventy peer-reviewed articles and book chapters. In addition to contributing to academic discourse, my work has also informed practical interventions and policies aimed at violence prevention.

7. Over the years, I have received numerous awards recognizing both my research and teaching excellence. These include the 2022 Faculty Excellence Award in Research Excellence, a 2021 nomination for the same, the 2020 Research and Scholarship Award, and multiple nominations for Professor of the Year and the CHHS Faculty Award. In 2018, I received the Dean's Faculty Research Innovation Award and the Junior Investigator Scholarship from the Academic Consortium on Criminal Justice Health. In 2015, I received the Student Award for Leadership and Service from the Group for the Advancement of Doctoral Education in Social Work for my work in bringing the Green Dot violence prevention program to Florida State University.

8. I have also received targeted funding to support my professional development and reduce student loan debt. I was a recipient of the NIH Loan Repayment Program from August 2022 through August 2024 and previously received the $40,000 Faculty Loan Repayment Program award from HRSA in 2017. Additional support includes a Safe States Scholarship in 2017 for CDC-led training and other awards that have strengthened my contributions to research and public health.

9. I have served as Principal Investigator ("PI"), Co-PI, and Co-Investigator on a range of externally funded projects focused on violence prevention, substance use, and health equity. Currently, I'm a part of a $469,069 NIAAA-funded project to rebuild a peer support program for sexual and gender minority survivors of sexual violence. I am also Co-PI on a three-year, $415,769 grant from the National Institute on Alcohol Abuse and Alcoholism ("NIAAA") to develop and validate measures for the Bystander Intervention for Problematic Alcohol Use Model (BIPAUM), which is a phased approach that assesses the outcome and effectiveness of bystander intervention programs which aim to prevent problematic alcohol use. In addition, I serve as PI or Co-Investigator on major federally funded projects addressing suicide prevention, child sex trafficking, and women's health systems, including multi-year awards totaling more than $3 million.

10. I am a member of the American Public Health Association and pay $210 in annual dues.

11. On April 24, 2024, I received notice that my institution was awarded a R15 grant (a grant awarded to institutions with a small amount of NIH funding, to develop their research portfolio) from the NIAAA in support of my research, for over $450,000 over a three-year period, to support my project titled *Reconstruction of an SGM-specific sexual violence peer support program*. This grant, which I spent six years developing, would also help to train students interested in research.

12. A true and correct copy of the notice of award is attached as Exhibit A.

13. This project researched ways to improve healing for sexual and gender minority survivors of sexual violence, given the substantially higher rates of sexual violence this community experiences compared to their heterosexual, cisgender peers. The project expanded upon the successful findings from one of my colleagues, who developed more generalized intervention approaches. The project consisted of three phases. The first phase aimed to conduct focus groups with sexual and gender minorities to modify the general intervention program content created by my colleague. The second phase aimed to distribute interventions to the community to determine if they were workable. The third phase would pilot a clinical trial to improve social reactions in comparison to a group who did not receive the intervention. If it showed significance, the modified intervention could help the most vulnerable victims feel safe enough to seek formal support and minimize the chances of revictimization.

14. This project was staffed by five undergraduate students and one graduate student.

15. I have spent countless hours over six years developing this project. The preparation was so intense that after completing my first application, I went out to celebrate just the act of submitting the application. The preparation consisted of researching, writing, and editing sections of my proposal on significance, innovation, and approach, as well as training opportunities and securing data. But NIH did not grant the award in response to this initial submission. I applied at least five times before my application was granted. Each time the application was sent back, I worked to incorporate feedback from NIH to adjust the parameters of the project to be completely in line with NIH historic goals, which emphasize incorporating marginalized communities into specific studies. The NIAAA specifically works on the connection between sexual assault and substance abuse, which is directly addressed in this study.

16. So far, we have nearly completed the first phase of the project. During that first phase, the project students worked with twenty-nine focus group participants. The participants were

members of the minority communities we are aiming to create new interventions for, and we presented ideas of approaches to the participants to solicit feedback on how they would respond.

17. On March 20, 2025, less than a year after NIH awarded this grant, I received a notice of grant termination stating that the award "no longer effectuates agency priorities." A copy of this termination notice is attached as Exhibit B.

18. The termination notice does not include any individualized explanation for why the grant was cancelled, and it fails to discuss any of the data or analysis from our application, annual progress reports, or other related material. Instead, the notice includes the following language about its decision:

> This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.
>
> Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision," no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Ex. B.

19. Prior to receiving this termination letter I was never given any notice that my grant was in jeopardy. In fact, the grant was on track to get a diversity supplement awarded.

20. I do not understand what the termination notice means by "gender identity," nor do I understand how my project was "based on" "gender identity." I also do not know what "biological realities" means in the notice. My project includes transgender participants, but was focused on studying the effectiveness of intervention tools.

21. My project included an SGM component in accordance with the priorities of NIH, which designate SGM as a health disparity population for research, indicating that research concerning this group is an important focus area. My project directly addressed the effectiveness and development of tools of intervention on this population, but was centered on the actual development and effectiveness of the tools and not on the concept of gender identity.

22. In my decade of research experience, before February 2025, I had never heard of an NIH grant getting terminated for anything other than fraud and misconduct.

23. I have never had a grant terminated by NIH before this one.

24. The impact of this termination on myself, my co-researchers, and my student staff is severe.

25. It is now uncertain whether my co-researchers and I will have the necessary funding to continue our critical research. While our institution has agreed to temporarily cover the salaries of the students who were working under this grant, this support is only short-term. Currently, the university is funding only one of the six students—a graduate student—while the undergraduate students will only be paid through the beginning of May 2025. At that point, absent sufficient funding for the project, these students will no longer be able to continue their work, which may effectively end their budding careers in research. I do not at this time anticipate being able to secure sufficient funding for this project after this short-term funding ceases.

26. This uncertainty has had a profound impact on the morale and well-being of the team. The students are not only grappling with the loss of financial stability but many of them are now questioning their decisions to pursue careers in public health—a field they once felt passionately committed to. Several are themselves sexual or gender minorities and feel personally attacked by the government, which has undermined their sense of belonging within the field. The research field cannot afford to lose young and eager researchers, especially ones with diverse backgrounds, which has immeasurable benefits to the field of scientific research and understanding.

27. The loss of this grant has also eliminated the $4,728 that was allocated for my 2025 summer salary, meaning I will no longer be compensated for continuing this work during the summer months. As a result, I am faced with the difficult choice of either doing the work without compensation or seeking additional research contracts to make up for the lost income, taking away time to for this research. This disruption comes at a critical point in my career as I am actively working toward promotion from Associate Professor to Full Professor. This promotion is not only a recognition of my academic accomplishments, but also affects my future earning potential and academic prestige. The termination of this grant may impede the timely completion of my research, thereby jeopardizing my ability to achieve this promotion and negatively affecting my long-term career trajectory.

28. In addition to the uncertainty around my career and professional opportunities, the loss of funding is significantly impacting my personal life. I am having to reconsider significant life events

that I had planned, including a wedding and sending my child to pre-school, because I do not have an idea of how much money I will have after this termination.

29. This increased workload and lack of adequate funding makes it impossible to sustain the research project. If this project is not completed, I will be unable to achieve its essential goal—training individuals to respond more effectively when a sexual or gender minority discloses that they have been a victim of sexual violence.

30. Because of the termination of the award, we are not able to complete phase one of the project, meaning that we are unable to do anything with the data analyzed from our focus group responses. If we had sufficient funding, we would have been able to change the program based on the data and then track the effectiveness of the program adjustments. Instead, now that we have lost funding, the data will be analyzed but will not be able to be disseminated via publications and conference presentations, and we will not be able to effectively apply the lessons we have learned from the data, making it essentially useless for the purposes of this program intervention.

31. It is well documented that inadequate responses to such disclosures regularly retraumatize victims of sexual violence, which can, in turn, increase their vulnerability to further sexual violence. The cancellation of this grant has not only disrupted my professional trajectory but has also jeopardized vital work aimed at addressing an urgent public health issue.

32. There is currently a significant gap in interventions—particularly those that equip peers with the tools to respond effectively and compassionately to disclosures of sexual violence. While there are numerous formal interventions in place, when I speak to people on the ground, what I hear again and again is a yearning for something more practical and human: a training that truly prepares peers to handle these disclosures with care.

33. Our work aimed to fill that gap by creating an inclusive and genuinely effective intervention, designed with the most vulnerable members of our community in mind. If we can support those at greatest risk, the benefits will ripple outward—ultimately creating a safer, more empathetic environment for everyone. This approach not only aligns with values academic institutions claim to uphold, such as student well-being, equity, and community engagement, but also holds incredible potential for expansion. Once refined, it could be scaled into online programs and implemented broadly across college campuses, reaching students nationwide. The potential impact is both immediate and far-reaching. But now, because of this termination, the potential

benefits the research could provide will remain unrealized due to our inability to properly apply and assess data driven programmatic changes.

34. Tied to this R15 grant awarded is an application for a $162,000 research supplement to promote diversity in health-related research, designed to support an early career trainee on our research team. The NIH program officer assigned to our project initially expressed concern that the trainee's project might be too broad in scope, but after the initial NIH review, we received a very positive review from the same NIH program officer. Soon after, NIH began sending requests for additional documentation—typically a sign that a Notice of Award was being prepared. Then, abruptly, all communication about the diversity supplement ceased after January 30, 2025.

35. For the past three months, there has been no update on the supplement's status, and during this period, the funding opportunity announcement expired. This grant would have fully supported the trainee's tuition and stipend through the completion of their dissertation, and its absence leaves both the student and our research program in a state of uncertainty and disruption. This supplemental work cannot be accomplished without the funds. Not only will the young researcher lose out on valuable research experience and development, but the project will suffer from not having enough staffing to adequately implement and track the effectiveness of the potential new intervention strategies identified in the focus groups.

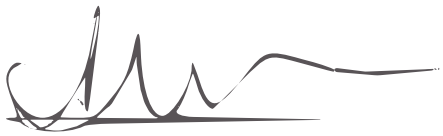
36. I supported the PI in appealing the termination of the R15 on April 17, 2025.

37. Even though we appealed the termination, I was uncertain how to address NIH's assessment that my project "no longer effectuates agency priorities," including because I do not understand in what sense my research is "*based on* gender identity."

38. I also do not know whether my appeal has any chance of success, given the language of the termination notice that "[t]he premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities." Ex. B.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 23 day of April, 2025.



Annelise Mennicke

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)

DECLARATION OF UAW PRE-MEMBER 1

I, [redacted], pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am a postdoctoral research fellow, performing scientific research in biochemistry and genomics. As a postdoctoral fellow, I work in a scientific lab that is run by a professor who acts as my mentor. Additionally, I am developing the leadership and scientific skill set to move to the next stage of my career as an assistant professor, where I will run my own laboratory.

2. I have wanted to be a scientist since the first science class I took in middle school. I was fascinated by trying to understand how living things work, and I enrolled in every science and math class offered in my high school. When I first had the opportunity to do biology research in a high school summer honors program, I loved it and knew that I wanted to pursue a career in science. To that end, I majored in molecular biochemistry and biophysics in college, and performed research in labs starting in the summer after my freshman year. After college, I enrolled in a biophysics PhD program, where I took courses and performed research in a lab run by my thesis adviser. I published multiple papers during my PhD training, and earned my degree in 2017. I then began my postdoctoral training, where I worked in a different mentor's lab, to learn new scientific approaches and gain additional expertise. I have gone through this extensive training period with the goal of being of a professor and running my own scientific laboratory. This is my career goal because it will enable me to continue to perform the scientific research that I love, as well as teach and mentor students. I know from my experience how important and influential engaging science teachers are in a student's life, and I want to pay it forward and play that role for the next generation of students.

3. I am approaching the end of my postdoctoral training at [redacted] and have received a job offer to begin my own independent lab as an assistant professor in the fall at [redacted].

4. I was awarded an NSF Graduate Research Fellowship during graduate school, and was supported by a T32 training grant at the end of my graduate training. I was also supported by a separate T32 training grant in the beginning of my postdoctoral period, and by a private foundation postdoctoral fellowship.

5. I am offering this Declaration in my individual capacity and not on behalf of my employer.

6. I am a member of [redacted], which is part of United Auto Workers (UAW). This means I signed authorization cards, in 2023 and 2024, expressing unqualified support for UAW to serve as my exclusive bargaining representative in dealings with my employer, [redacted]. I also voted in support of UAW during an NLRB election in April 2024. UAW is currently representing me in negotiations with [redacted] for a first-time collective bargaining agreement (CBA) that will govern the terms and conditions of my employment at [redacted] Once our CBA is finalized, I intend to be a full, dues-paying UAW member.

7. I was awarded a Maximizing Opportunities for Scientific and Academic Independent Careers K99/R00 Postdoctoral Career Transition Award to Promote Diversity (MOSAIC grant) by NIH through the National Institute of General Medical Sciences (NIGMS). The grant award number is 1K99GM[redacted] and the Notice of Award (NOA) for the grant is dated January 5, 2022. A true and correct copy of the NOA is attached hereto as Exhibit A. This grant is known as a pathway to independence grant – I was awarded two years of postdoctoral funding (the K99 period) to support the end of my postdoctoral training, and three years of funding for my independent lab (the R00 period) that I can activate when I find an independent position as an assistant professor. These awards are designed to facilitate the process of transitioning from a postdoctoral position to independent faculty – a process that is notoriously difficult, given the scarcity of faculty job positions.

8. I study how cells in the human body communicate with each other during development, and how this goes awry in disease. Specifically, I want to understand at a molecular level how cells change which genes they express in response to signals from other cells. This process is essential for development, and often is inappropriately regulated in diseases like cancer. By better understanding the regulation of gene expression, I hope to identify possible cancer therapeutic strategies.

9. The MOSAIC program is a specific type of the generic, or parent, K99/R00 award that is designed to increase the participation of scientists from under-represented backgrounds in academic

science, by facilitating the transition to faculty for scientists who will promote diversity in academia. A true and correct copy of the announcement of this funding opportunity, PAR-19-343, is attached as Exhibit B. I have been dedicated to promoting the inclusion of women in science throughout my scientific training – I ran a mentoring program for women in science during my graduate training and contributed to the development of parental leave and Title IX policies in my graduate institution. I have also been committed to mentoring students from under-represented backgrounds in laboratory research. I wrote about these past experiences and my plans to continue to work to support the inclusion of scientists from all backgrounds in my future career in the diversity statement in my application. Additionally, I belong to two of the NIH's defined categories of groups underrepresented in science: [redacted] I felt that I was a good fit for the MOSAIC program and decided to apply to it instead of the standard K99/R00 program. I was particularly excited about the fact that the MOSAIC program works on a cohort model – awardees were encouraged to form a network of early career scientists who excel in their fields and are dedicated to making academia more inclusive. Additionally, fellows would be able to participate in professional development training opportunities arranged by scientific societies supported by the MOSAIC-UE5 grants. I thought that being a part of this network would help me be a better professor in my future, as I would be able to learn from the peers in my cohort about how to best lead a laboratory, and we would support each other through this transition to independence.

10. I spent about 5 months preparing the materials for my K99/R00 application. The application required a scientific proposal, a specific aims page, a training plan, a biosketch (essentially a resume in NIH format), mentoring plans from my mentors, letters from my collaborators, recommendation letters, a diversity statement, a description of the institution environment of my postdoctoral institution, commitment from my department to support my training, a plan for training in responsible conduct of research, a plan for sharing of resources with the scientific community, and a budget. In all, my application was 87 pages long. I extensively discussed the scientific plan with my lab mentors and got feedback on my application from many mentors. As I was beginning my work on this proposal, I discussed my application with the program officer (PO) for the grant to ensure that my application aligned with the types of science that they intended to fund.

11. I have finished both years of the K99 portion of my grant and have been planning to apply to activate the R00 portion of my grant this summer, once I have officially accepted a faculty position as an assistant professor.

12. The two years of K99 funding enabled me to collect large genomic data sets during my postdoc, which I published in the major academic paper from my postdoctoral training. This funding also allowed me to present my findings at academic conferences, which is an essential step in the process of finding a faculty position. I also have been able to form a network with other MOSAIC K99/R00 fellows through some of the professional development opportunities arranged by the program. Additionally, the cohort of fellow awardees in my local area have supported each other through the job application process, which has been immensely helpful for all of us.

13. In the beginning of April 2025, I heard from other MOSAIC K99/R00 awardees that they had received an email from their Program Officer that the MOSAIC program was canceled. I did not get an email at this time, and not all NIH institutes sent out these warning emails at the same time.

14. However, on April 11, 2025, I received an email from Kenneth D. Gibbs, Jr., Director of the Division of Training and Workforce Development at the NIGMS entitled "NIGMS Funding Update" notifying me that the MOSAIC program had been "terminated" "due to changes in NIH/HHS priorities." A true and correct copy of the email is attached hereto as Exhibit C.

15. I was not given any individualized explanation for the cancelation of my grant. I was simply told that the MOSAIC program as a whole is being cancelled.

16. I was simply told that the MOSAIC program was being canceled due to changes in NIH/HHS priorities. I understood this to mean that this is due to the diversity focus of the MOSAIC program, given that the non-MOSAIC K99/R00 awards were not canceled

17. My scientific project is not "based on" "DEI"/ "amorphous equity objectives" or "gender identity". I study gene expression in cancer cells. The MOSAIC program considered an applicant's commitment to promoting diversity in science in addition to the excellence of their scientific proposal and research experience, and I understand this to be the reason behind my grant cancelation.

18. My scientific project does not specifically acknowledge minority groups or demographic differences.

19. My understanding of R00 activation in the past was that it was an administrative process – applicants would email their PO with information about their job offer, their new institution, and their budget, to show that their new position and institution would support them and their research. The scientific merits of my grant were already reviewed and positively evaluated when the decision was made to fund my award in 2022. If not for the cancelation of the MOSAIC program, I do not anticipate that I would have had any difficulty activating my R00 award at my new institution.

20. I have applied for academic faculty job positions under the assumption that I will be able to activate my R00 funding. The promise of this funding made me a more competitive candidate because I would bring in funding to kick-start my lab, and it showed that I have a successful track record of applying for and being awarded NIH funding. Now, I no longer have the funds, and there is a concern that I will be unable to obtain future funding, given that I have received an award that is considered a "DEI grant". Therefore, without this funding I am now a less competitive candidate for academic jobs. I have received a job offer to begin my own independent lab as an assistant professor, but the offer is not yet finalized. Without my grant funding, my new institution may rescind the job offer.

21. If I am able to start my independent position this fall, not having my R00 funding will reduce the total starting funds I have to begin my independent lab by about 42%. This will vastly impair what I am able to do in the lab. I was planning to use the R00 funds to hire a technician to work in my lab – now I will not be able to hire a technician until I obtain additional grant funding. I also planned to use the R00 funding to purchase equipment and experimental supplies, that I now will not be able to purchase. Additionally, having the R00 funding gave me some freedom to focus exclusively on setting up my lab and mentoring my first students. Now, I will have to devote time immediately to applying for other NIH and private foundation grants to fund my lab. This is time I will not be able to devote to teaching my first students how to do experiments in the lab, which will also impair their training and scientific development. In all, this means that my ability to get my new lab up and running will be severely impaired. The consequences of this slow down for my career include the fact that I will have a more difficult time achieving tenure. If I cannot get tenure within a set time period after starting my academic position, I will not be able to keep my job. Tenure is evaluated based on scientific progress and grant funding – not being able to devote the beginning of my lab time to scientific work means I will likely publish fewer papers before I go up for tenure, and will reduce the amount of preliminary data I will be able to generate to include in other grant applications. Beyond the effects on me and my career, this reduction in funding will reduce and impair my scientific output and discoveries.

22. I have not appealed the termination because my grant itself has not been terminated yet, although I am aware that the MOSAIC program has been canceled and my grant will be terminated. I do intend to appeal when I receive official termination notice. However, I do not believe the appeal has any chance of success, given the stated change in NIH and HHS priorities away from any "DEI" projects.

23. I wish to file my declaration under seal because I am concerned about being blacklisted from future federal funding through the NIH, and the subsequent harm this would create for my career.

24. I have concerns about public hostility and harassment due to the current political climate. I am worried that I would be harassed and derisively labeled as a "DEI" hire with the implication that I am not as qualified as other scientists because of my participation in the MOSAIC program. My new job as an assistant professor has not yet been finalized, and I worry that being named in this suit could lead to my job offer being rescinded.

25. I also worry that I will be blacklisted from future federal funding opportunities, in particular from the NIH. NIH funding is absolutely essential to my career – the expectations for achieving tenure in academia are generally to have at least one active major NIH grant. If I cannot get tenure, I will lose my job as a professor. Additionally, collaborations are a major part of scientific research, including collaborating as co-investigators on grants. If I develop a reputation as being potentially blacklisted by the NIH, potential collaborators will view me as a risk and be less likely to work with me on scientific projects and grant applications. This will limit the scientific work I am able to complete in my career.

26. I have spoken with other MOSAIC scientists who have expressed similar fears as I describe above. MOSAIC scholars that are still attempting to secure a position as an assistant professor are concerned about drawing attention to this grant cancelation and reducing their ability to secure a job.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 19th day of April, 2025.

[redacted]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants.*	Case No. 1:25-cv-10787-BEM Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)

DECLARATION OF UAW PRE-MEMBER 7

I, [redacted] pursuant to 28 U.S.C. § 1746, declare as follows:

1. My name is [redacted] and I am a postdoctoral Research Fellow in the department of Genetics at Harvard Medical School. I graduated from [redacted] I am in the first year of a career development award from the National Institute of Health ("NIH"), and was previously funded by the [redacted] My postdoctoral studies are critical to my goal of ultimately obtaining an academic faculty position with my own research program at a university. Since 2018, I have co-authored six peer-reviewed articles, including two first-authored articles, on genetics and other biomedical topics in leading scientific journals.

2. I am offering this Declaration in my individual capacity and not on behalf of my employer.

3. I am a member of Harvard Academic Workers—United Auto Workers ("UAW"). This means I signed an authorization card expressing unqualified support for UAW to serve as my exclusive bargaining representative in dealings with my employer, Harvard. UAW is currently representing me in negotiations with Harvard for a first-time collective bargaining agreement ("CBA") that will govern the terms and conditions of my employment at Harvard. Once our CBA is finalized, I will be a full, dues-paying UAW member.

4. I am the recipient of a Maximizing Opportunities for Scientific and Academic Independent Careers K99/R00 Postdoctoral Career Transition Award to Promote Diversity ("MOSAIC grant") awarded by NIH through the National Institute of General Medical Sciences ("NIGMS"). The grant award number is [redacted] and the Notice of Award ("NOA") for the grant is dated [redacted] A true and correct copy of the NOA is attached hereto as Exhibit A.

5. According to the Notice of Funding Opportunity ("NOFO"), PAR-21-271, at 6, MOSAIC grants are issued by NIH "to enhance workforce diversity by facilitating a timely transition of promising postdoctoral researchers from diverse backgrounds ... from their mentored, postdoctoral research positions to independent, tenure-track or equivalent research-intensive faculty positions." A true and correct copy of the expired PAR is attached hereto as Exhibit B. The MOSAIC program is a specific type of the generic, or parent, K99/R00 award that is designed to increase the participation of scientists from underrepresented backgrounds in academic science, by facilitating the transition to faculty for scientists who will promote diversity in academia. The MOSAIC grant provides up to five years of support through two phases, funding up to two years of the MOSAIC scholar's postdoctoral research position (the K99 or "mentored phase") and up to three years of independent research support in a tenure-track faculty position (the R00 or "independent phase"). MOSAIC scholars apply for tenure track positions at institutions in the last year of the mentored phase, and once accepted to a position, the institution at which the scholar will become faculty submits the application for the independent phase. The program announcement for the MOSAIC grant states that receipt of the R00 phase of the award "is contingent on satisfactory progress during the K99 phase and an approved, independent, tenure-track (or equivalent) faculty position. The two award phases are intended to be continuous in time." Id. at 7.

6. MOSAIC grants provide funding both for salary support and research support during the mentored phase. During the independent phase of the award, the MOSAIC grant provides funding for salary and benefits, research costs, and indirect costs reimbursed to the R00 sponsoring institution. The R00 sponsoring institution also commits to providing start-up funds to help the MOSAIC scholar set up their laboratory and some other institutional support. In addition to funding, MOSAIC scholars are provided with mentoring, networking, and professional development activities.

7. I initially applied for the MOSAIC grant on February 12, 2024. The grant is extremely prestigious and competitive, requiring me to go through a rigorous review process before I was selected. My application was 88 pages long, and it took me a month to draft the research statement and assemble the necessary documentation. I also had to submit supplemental information about my project, called "just in time information", before my project was ultimately approved. My grant application included a diversity statement that discussed my previous work advocating for diversity, equity, and inclusion in biomedical sciences, including serving on numerous committees in my graduate institution to promote diversity and improve working conditions for researchers, creating a virtual symposium on diversity in science in 2020, and creating resources to help first generation graduate students navigate graduate school. I also discussed that I am a queer and disabled woman in science, as the NOFO and accompanying NIH information discussed that women and people with disabilities are underrepresented in the field of biomedical research science. Exh. B.

8. My research project studies the role of molecular capacitors in obscuring genetic variation. My work currently focuses on the [redacted] I am currently in the first year of the mentored phase of my project, which began [redacted] in which I have been using gene knockouts in zebrafish to identify [redacted] In the seven months since receiving this award, I have established novel gene-knockout lines for 33 alleles across 13 [redacted] candidate genes, collaborated on developing an automated pipeline that measures [redacted] in fish, and identified two previously unreported gene knockouts that [redacted] and two previously unreported knockouts that [redacted] During the independent phase of my project, my NIH-approved research plan contemplated that I would investigate the role of [redacted] in development by abrogating its activity in developing zebrafish to identify tissues and pathways that are sensitive to [redacted] To that end, I have also, during the first year of my award, generated test-case transgenic zebrafish lines that carry dominant-negative [redacted] expressed in a tissue specific manner.

9. My NOA states that the project period for the mentored phase of my grant runs from [redacted] until [redacted] with the first year budget period running until [redacted] Exh. A at 1. The award for the first year was [redacted] and the NOA recommends that the second year budget award be the same amount, "subject to the availability of funds and satisfactory progress of the project." Id. at 3. As detailed above, I have made excellent progress on my project.

10. On April 2, 2025, less than a year into my MOSAIC grant, I was extremely distressed to receive an email from Kenneth D. Gibbs, Jr., Director of the Division of Training and Workforce Development at the NIGMS titled "NIGMS Funding Update" notifying me that the MOSAIC program had been "terminated" "due to changes in NIH/HHS priorities." A true and correct copy of the email is attached hereto as Exhibit C.

11. The email also states that my "institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions."

12. On [redacted] I sent an email to the general email address for NIGMS Training that had been provided, to seek clarification of the April 2, 2025 Gibbs email. The following day, on [redacted] I received a response from an unnamed person using the NIGMS Training email address. In response to my inquiries, the unnamed person using the NIGMS Training email address replied inline to my email by writing answers in bolded type directly into the body of the email that I had sent. A true and correct copy of the email I received from NIGMS Training is attached hereto as Exhibit D.

13. In response to my question whether my institution will be able to draw down funds through the duration of my project term for the mentored phase of the grant or whether the April 2nd email from Mr. Gibbs constituted a notice that my grant will be terminated, the email from NIGMS Training states "**The email provided updates on future NIGMS funding for certain programs that are no longer supported due to NIH/HHS priorities. NIH staff will follow up with specific information or action needed regarding any individual award. The award will terminate *no later than* the end of the current budget period. However, *awards may terminate sooner* based on NIH/HHS priorities. When awards are terminated, grantees will receive a revised notice of award.**"

14. I had also inquired whether MOSIAC R00 awards would no longer be made and if so, whether I could apply to transition to parent R00 grants. Transitioning to a parent R00 grant would allow my funding to continue through a different grant line. In response to my inquiry, the email from NIGMS Training states "**The R00 will not be made, and awardees cannot transfer to the Parent K99.**"

15. The termination of the MOSAIC program, and my loss of funding past the current budget year—ending [redacted]-has sent my career into a tailspin. I have dedicated an enormous portion of my time since the April 2nd email, perhaps 15 hours a week or more, to seeking clarity from my mentors about their expectations, researching alternate sources of funding, and networking with other disenfranchised scholars to form plans for our futures, which has slowed the pace of my research significantly. Although my mentors have made personal guarantees to find funding for me to continue my research, their lab budgets were predicated on my salary being paid by this grant, additional NIH funding cannot be guaranteed, and my institution does not seem to have a plan to provide any bridge funding to postdoctoral fellows who have lost funding. Not only is my current position precarious, but the loss of potential R00 funds will certainly have an impact on my ability to secure a tenure-track position in two years. Competition for academic positions is fierce and bringing in funding in the form of an R00 grant markedly increases the chances of securing a position. On a personal note, this news has been heartbreaking, and the stress incurred has had impacts on my sleep, motivation, and focus.

16. The loss of this grant will also have a horrible impact on my work, which has important implications for research into the genetic determinants of development and disease within individuals and across populations. One of the great outstanding questions in the study of genetic disorder/disease is why some people who carry a given mutant allele have symptoms of the associated disorder while other individuals who carry the same mutation remain healthy. My work aims to create a model system to interrogate the role of chaperone proteins on obscuring/revealing genetic variation, which I hypothesize may play a role in determining the circumstances in which "disease" alleles actually result in disease traits. My work has the potential to offer novel insight into the environmental circumstances and molecular mechanisms that trigger the revelation of mutations, including those mutations that result in genetically associated human diseases and disorders.

17. I am also very concerned about the long term impact on my generation of scientists who are dependent on these awards to launch a career dedicated to research, scientific development, and progress on the core medical issues of our time. Without the MOSAIC program and other NIH programs like it, far fewer scientists will be able to choose this path. Perhaps even more importantly, there will be a *specific* loss of scientists who are dedicated to improving mentoring, teaching, outreach, and workplace conditions in STEM. The MOSAIC program was explicitly intended to combat the "diversity tax," which describes the phenomenon where minorities tend to do proportionately more outreach and mentoring. Exh. B at 7. Not only will the loss of this funding result in the loss of brilliant scientists in my cohort who would have been my colleagues, collaborators, mentors, and mentees, and whose research would have been transformative in the biomedical field, but it will have generational consequences as we diminish the number of researchers dedicated to fostering an inclusive environment for the next generation of thinkers.

18. I am currently looking into ways to appeal, but I do not know the chance of success. The research I proposed is research that would have been fundable under the parent K99, however, having been awarded the MOSAIC, I am now ineligible to apply for any other K grant, even if I do not receive the funds that I was awarded. The MOSAIC grant funds brilliant basic and translational research that has the potential to transform our understanding of health and disease—exactly the mission of the NIH. I do not understand how the MOSAIC program is incompatible with agency priorities.

19. I am seeking to file this declaration under seal because I am concerned about public hostility to my involvement in litigation against the NIH. I am worried about long term impacts on my career, both with the potential of being blacklisted from other funding opportunities and for the potential of making it more difficult to secure a faculty position. I am also worried about the potential for retaliation against my institution, as well as against my faculty mentors, and am concerned about negative impacts on their ability to get funding both as individuals and also for their labs.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 20 day of April, 2025.

[redacted]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH, *et al.*,

Defendants.

Case No. 1:25-cv-10787-BEM

Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)

DECLARATION OF UAW MEMBER 3

I, [redacted], pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am a Postdoctoral Research Scientist at [redacted]. My field of study is [redacted].

2. I am a postdoctoral researcher in the [redacted] and the [redacted]. I hold a Ph.D. [redacted] and a B.A. [redacted].

3. I have been continuously funded during my career. I have previously received fellowships from [redacted], and [redacted].

4. I am offering this Declaration in my individual capacity and not on behalf of my employer.

5. I am a dues-paying member of [redacted], which represents postdoctoral researchers at [redacted].

6. On June 12, 2024, I applied to the National Institute of [redacted] for a MOSAIC K99/ROO grant.

7. The MOSAIC program is a K99 mechanism to fund scientists who are underrepresented at the faculty level by race, gender, and socioeconomic status. This grant also requires a diversity statement where the applicant describes their personal background and what they have done to expand access to science, mentorship experience, and public outreach. If funded, the MOSAIC K99 has a UE5 program that connects awardees with peers and mentorship for the duration of their award. I was also eligible for the Parent K99, which does not include a diversity statement or UE5 program. However, I wanted the additional mentorship that comes with the UE5 program and wanted to highlight my strengths as a candidate with substantial experience in scientific outreach, so I decided to apply for the MOSAIC program.

8. The Notice of Funding Opportunity (NOFO) for the MOSAIC K99 to which I applied indicates that individuals who are underrepresented in the biomedical sciences are eligible to apply. A true and correct copy of PAR 21-271, which announced this funding opportunity, is attached as Exhibit A. As a woman, I am underrepresented among biomedical science researchers. I cited this criterion in my application. I am also a U.S. citizen and was eligible for the MOSAIC K99.

9. The MOSAIC K99 provides two years of postdoctoral funding followed by the opportunity to apply for the R00 phase which provides three years of funding in an independent lab (almost always funded). My proposal is focused [redacted].

10. The title of my proposed research topic for the MOSAIC award is "[redacted]." The narrative describing my proposal, as conveyed in my MOSAIC application, explains that [redacted]

11. On November 18, 2024, my proposal was formally reviewed by a study section. Study sections are groups composed of faculty from US PhD-granting institutions with scientific expertise related to the proposal. My particular study group has expertise related to the mission of [redacted] including [redacted]

[redacted] which are directly related to my proposal. My grant was first reviewed by three faculty on the study section whose identities I do not know. My grant was then discussed with the larger study section on November 18, 2024, and scored.

12. On November 18, 2024, the study group assigned to review my proposal gave it an Impact Score of 10, which is a perfect score. Each of the three initial reviewers scored the components of my grant, including my strengths as an applicant ("Candidate"), the plan to transition to an independent faculty position ("Career Development Plan/Career Goals/Plan to Provide Mentoring"), my proposed research ("Research Plan"), my mentorship team ("Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)"), and the quality of the scientific training environment at the [redacted] ("Environment Commitment to the Candidate"). The scoring system is 1 to 9, where 1 indicates exceptional and 9 indicates poor. After discussion of my application on November 18, 2024 with the larger review panel, reviewers privately vote on an overall impact score, 1-9. The final Impact Score is calculated by averaging the normalized impact score of all reviewers, then multiplied by 10. Thus, the final Impact Score is on a scale from 10 to 90, where 10 is exceptional and 90 indicates poor.

13. On December 16, 2024, I received the summary statement issued by the study group. That statement was glowing, [redacted]

14. On February 6, 2025, the advisory council was scheduled to consider my proposal. The [redacted] Advisory Council is composed of leaders in science, education, health care, and public affairs, including faculty at PhD-granting institutions and NIH employees. Its members are appointed to 4-year terms and meet three times per year to perform a second level of peer review for grants and offer recommendations on grants to fund. The February 6 meeting, however, was cancelled, as I learned from an NIH official. I received no notice of why it was cancelled.

15. From late January 2025 through March 2025, I regularly emailed and called NIH about my MOSAIC application but was routinely ignored.

a. On [redacted], I contacted the program officer for my MOSAIC K99 application, [redacted], to understand the status of my MOSAIC application. I received no response.

b. On [redacted], I emailed [redacted], another NIH official in the Division of Training and Workforce Development, to ask if I could reapply for the Parent K99. The parent K99 is the same funding opportunity but eligibility is not limited to those who

are underrepresented in the biomedical work force and it does not have a diversity statement or UE5 program. I received no response.

c. On [redacted] I emailed [redacted] to ask about the timeline of K99 funding because I was at risk of being laid off. I wrote again on [redacted]. I received no response to either email.

d. I also called [redacted] office to discuss my MOSAIC application on [redacted] No one ever picked up nor did anyone ever return the few voice messages I left.

16. I am no longer eligible for the Parent track of MOSAIC track applications. I lost my eligibility on [redacted] This is because the Parent and MOSAIC K99 eligibility windows are four years from the start date of the postdoctoral training period, and I started my position on [redacted].

17. It me considerable effort to assemble my MOSAIC application. I worked full-time over eight weeks to put it together. It entailed finding collaborators, mentors, and writers for letter of recommendation. I had to write documents, compile references, and construct figures to describe my career accomplishments, research proposal, training plan, and career plan as a faculty member. These documents are highly technical and require multiple rounds of revision and review from trusted mentors, peers, the [redacted] grant office, and colleagues. My grant was [redacted] pages in total.

18. That process entailed speaking with NIH program officers to determine the correct NIH institute where I should apply. I reached out to program officers at five institutes between October 11, 2023 and October 24, 2023, totaling 30 emails, to see if my research was a good fit for the institute. I also determined if I should apply to the parent K99 or the MOSAIC K99 (I was eligible for both) by meeting with our internal grants team at the [redacted] on May 9, 2024 and August 21, 2023.

19. Grant applications with perfect scores are always funded, except for extremely rare circumstances, such as accepting another award. This is according to my NIH program officer (PO), the grants office at the [redacted] and my own experience with NIH and NSF. Thus, I, the grants office at the [redacted], and my mentors fully expected that I would receive a notice of award (NOA) on February 6, 2025, and that my grant would start on April 1, 2025. These are the standard dates by which NIH has, according to its website, issued and disbursed awards in the past. A true and correct copy of the NIA K99/R00 webpage (last visited on April 18, 2025) including its award cycle is attached as Exhibit B.

20. On February 27, 2025, an anonymous NIH employee called me and we had one conversation about my MOSAIC K99 application. That employee revealed to me that they were instructed by

leadership at NIH that they are not allowed to respond to emails or discuss via email or phone anything to do with MOSAIC K99 applications. This is consistent with my email interactions with NIH employees who have only responded to my emails about the parent K99.

21. My boss, [redacted], cannot afford to pay me because like many principal investigators, he is waiting for grants to be reviewed or funded, including an R01 that would have funded my work, so my boss informed me at several weekly one-on-one meetings in February that without additional funding from my K99 or his R01, my contract could not be renewed. At this point I emailed the [redacted] (on February 28, 2025), [redacted] (February 7, 2025) to ask for emergency salary support. The [redacted] is paying my salary temporarily. So, I was almost laid off because of the loss of expected MOSAIC funding.

22. Given my need for funding I applied for and was granted an exception to reapply to the Parent K99 on February 12, 2025, which I did. The parent track, however, prejudices me in several respects. First, that cycle will be very competitive in that it will have more applicants than usual because BRAIN and MOSAIC applicants from the June and October cycles of 2024 have been advised—according to what the grants office at [redacted] shared with me--to re-apply for the Parent K99 for the February 2025 cycle; second, I will receive new reviewers meaning that the faculty who read my application will not have the context that I already applied for this award, and, third, none of my reviews from my MOSAIC K99 application – which resulted in a perfect score – will transfer to this new application despite it being for the exact same research.

23. Finally, the earliest I will receive funding for the Parent K99, if granted, is December 2025, which will count as eight months without NIH funding.

24. The long-term consequences of this loss of funding cannot be understated. This loss of salary has meant that I have needed to apply for faculty positions sooner than I intended, given that I have at least two more years of work needed to complete my postdoctoral research project. If I start a faculty position before my postdoctoral research is complete, I will have to finish it in my own lab, which will occupy the first one or two years of my time on the tenure track. This is not good. While on the tenure track, assistant professors are expected to establish an independent line of research from their postdoctoral advisor and generally papers published with postdoctoral advisors as co-authors do not count toward tenure. Thus, potentially as many as two of my seven years on the tenure track would be spent on research that should have been completed during my postdoc. This reduces my chances of getting

tenure after seven years as an assistant professor. An assistant professor who does not obtain tenure must either get a new tenure track faculty job at another university or leave the academic profession.

25. Thankfully, the [redacted] has stepped up to cover my salary until December 2025. However, given the state of [redacted], I do not know how much longer my job will be safe. Additionally, without the expected MOSAIC funding, the study I proposed will not happen.

26. This proposed research is important because it could contribute to breakthrough advances in our understanding of [redacted]

27. Further, the R00 aim of my K99 proposes to apply what I learn about [redacted] This research stands to have major implications for public health.

28. I wish to file my declaration under seal because I fear that disclosure of my name will result in physical or mental harm and that it will result in reputational harm. I also have concerns about the public being hostile to my participation in this litigation given the current political climate.

29. If my identity were publicly disclosed, it would become public information that I was a whistleblower which could result in hiring committees at universities becoming biased against me for fear of me speaking out against my future institution.

30. I also fear being blacklisted from future federal funding opportunities. The current political climate is rife with vengeance against political adversaries. If the federal government decides to blacklist me from future federal funding, it would be extremely difficult to prove in the future. The current phase of my career is extremely time sensitive, so even short delays in funding, if NIH were to withhold funding due to my participation in this lawsuit, could cut me off from my salary and thus result in me having to leave my academic career.

31. I also fear that the NIH employee that contacted me could be the subject of retaliatory consequences if their identity were to be revealed given the mass layoffs that are currently happening at NIH.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this **21st** day of April, 2025.

[redacted]

[redacted]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)

DECLARATION OF UAW MEMBER 9

I, [redacted], pursuant to 28 U.S.C. § 1746, declare as follows:

1. My name is [redacted] and I am a postdoctoral fellow [redacted] I am in the first year of a postdoctoral fellowship in [redacted]'s Institutional Research and Academic Career Development Award ("IRACDA") Program, and my ultimate career goal is to teach neuroscience at an undergraduate university. I graduated from [redacted] with a PhD in biomedical sciences, where I focused on the acute behavioral deficits observed after mild traumatic brain injuries and [redacted] During my graduate studies, I found passion for academic leadership, service, student advocacy, mentoring, and teaching. Since 2018, I have co-authored six peer-reviewed research articles on neuroscience published in leading scientific journals.

2. I am offering this Declaration in my individual capacity and not on behalf of my employer.

3. I am a dues-paying member of United Auto Workers ("UAW") [redacted]

4. [redacted]'s IRACDA program is funded by the National Institute of Health ("NIH") through the National Institute of General Medical Sciences ("NIGMS"). The grant award number is [redacted] A true and correct copy of an excerpt from NIH's RePORTER webpage containing information about [redacted]'s grant is attached hereto as Exhibit A.

5. According to the Notice of Funding Opportunity ("NOFO"), PAR-19-366, at 2, the purpose of the IRACDA Program is to train postdoctoral scholars in both research and teaching by providing "support for a mentored postdoctoral research experience at a research-intensive institution combined with an opportunity to develop critical teaching and mentoring skills at a teaching-intensive partner institution with a diverse student population." A true and correct copy of the expired PAR is attached hereto as Exhibit B. The goals of the IRACDA program are both to provide research and mentored teacher training for the IRACDA scholars, while also benefiting colleges serving populations that are underrepresented in biomedical research by "providing research-oriented, early career teachers, mentors, and role models for the students; enhancing science educational offerings; providing research opportunities for the faculty and students; and/or bringing expertise with state-of-the-art research methods and technologies." Id.

6. NIH IRACDA grants are awarded directly to a higher education, research-intensive institution that works in partnership with a teaching-intensive institution. [redacted]'s IRACDA Program partners with [redacted], a Hispanic-Serving Institution.

7. [redacted]s IRACDA Program is a four-year program. IRACDA institutions receive NIH awards to provide scholars with "funding for up to three years provided their progress toward an independent academic career is on track and satisfactory," and NIH encourages institutions to use non-IRACDA funds to supplement the three years of NIH-funded support with an additional year of funding to provide for a four-year program. Id. at 4.

8. I began my four-year postdoctoral fellowship in [redacted]'s IRACDA Program in September 2024. A true and correct copy of my offer letter for the first year of my IRACDA fellowship is attached as Exhibit C. Since beginning my fellowship at [redacted], I have continued my research into brain injuries, researching the mechanisms at play in female specific traumatic brain injuries. I have contributed to and lead three undergraduate researchers on a project investigating [redacted] symptoms experienced by females after traumatic brain injury. I have presented my research to leading brain injury experts in [redacted] and my fellow IRACDA post-doctoral fellows, and I had an abstract accepted to present at the [redacted] meeting this year. I have also begun teacher training at [redacted] in a class entitled [redacted]

[redacted]" and have been co-teaching a biomedical journal club at [redacted] with my fellow IRACDA postdoctoral scholars.

9. My research is important because millions of Americans suffer traumatic brain injuries every year, imposing vast health, social, and economic costs. Half of all hospital visit traumatic brain injuries are experienced by women, so my current research aims to discover better ways to treat the injuries and symptoms that women specifically suffer from.

10. The current grant for [redacted]s IRACDA program had a project start date of [redacted] and end date of [redacted] Ex. A at 5. My understanding is that [redacted] would have filed for an extension to continue the IRACDA program past the [redacted] project end date. Yet on April 2, 2025, less than a year into my IRACDA fellowship, Kenneth D. Gibbs, Jr., Director of the Division of Training and Workforce Development at the NIGMS sent an email titled "NIGMS Funding Update" to a co-director of the [redacted] IRACDA program stating that the IRACDA program had been "terminated" "due to changes in NIH/HHS priorities." A true and correct copy of the April 2, 2025 email is attached hereto as Exhibit D.

11. The email also states that the "institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions."

12. On April 3, 2025, I received an email from the co-directors of the [redacted] IRACDA program stating that NIH had decided to terminate the IRACDA program and funding would officially end on [redacted]. The email states that my salary would continue to be supported only until [redacted] unless NIH decides to withdraw funding sooner. The email also states that [redacted] does not have alternative funding sources to continue the program beyond the date that funding is terminated and recommends that I immediately seek other funding. A true and correct copy of the April 3, 2025 email is attached hereto as Exhibit E.

13. The termination of the IRACDA program has had a terrible impact on my career. I will not have protected teaching time or the teacher training at an institution meeting my career goals that only the IRACDA offered, leading me to be less prepared for teaching in my career. I also no longer have my salary covered for my postdoctoral experience, requiring me to halt my research to urgently apply for alternative funding. If I am not awarded a new grant, I will have to find alternative employment outside of my scientific passion and area of expertise.

14. The termination has also had an enormous impact on me personally. I had relocated my family to [redacted] in order to do the fellowship. There is profound grief when you find out your expected future will not come to be and a lengthy process to reevaluate and make new plans. This new job uncertainty has delayed my plans for family expansion and added tremendous stress to my life.

15. I am also very concerned about the long-term impact on my generation of scientists who are dependent on these awards to launch a career dedicated to research, scientific development, and progress on the core medical issues of our time. Without the IRACDA program and other NIH programs like it, there will be far fewer people who can pursue a career in science research and teaching. In my program alone, there are eight IRACDA scholars studying a wide range of critical biomedical topics, all of whom have had their careers thrown into turmoil by the termination of the IRACDA program. The termination also negatively impacts the students at [redacted] They will no longer have a biomedical journal club aimed at building mentorship and preparing them for graduate school, they will no longer have IRACDA fellow-led evidence-based teaching interventions from our teaching as research projects, and they will no longer benefit from future professors who have specifically been trained to teach students with their educational backgrounds.

16. I don't know if my institution will be appealing the termination, and even if it does, I do not know the chance of success. Nor do I understand why the IRACDA program was cut and how it is incompatible with agency priorities.

17. I am seeking to file this declaration under seal because I am concerned that my participation in this lawsuit could lead to retaliation against me. In particular, I am worried that providing this declaration could hurt my ability to obtain federal funding in the future, including new NIH funding that I may seek to obtain later this year.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 25 day of April, 2025.

[redacted]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH, *et al.*,

Defendants.

Case No. 1:25-cv-10787-BEM

Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)

DECLARATION OF UAW MEMBER 10

[redacted]

5. The IRACDA program is funded by the National Institute of Health ("NIH") through the National Institute of General Medical Sciences ("NIGMS"). The grant award number for UCSD's

IRACDA program is 5K12GM068524-22. A true and correct copy of NIH's RePORTER webpage containing information about UCSD's grant is attached hereto as Exhibit A.

6. According to the funding opportunity to which I applied, PAR-19-366, the purpose of the IRACDA Program is to support postdoctoral scholars from diverse backgrounds in their transition to academic independence by combining research and teaching training. As described on UCSD's website, https://hsfacultyaffairs.ucsd.edu/sd-iracda-postdoc-program/index.html, the IRACDA program "provides three years of mentored training in post-doctoral research in biomedical sciences . . . mentored teaching training at our partner institutions [,] and development of critical academic skills needed to conduct high quality research and pursue an independent academic career. The IRACDA program aims especially to develop a diverse group of highly trained biomedical scientists. Other specific objectives are to innovate, redesign, and develop science curriculum at teaching-intensive partner institutions and to establish links between UCSD and our partner institutions to promote collaborations in faculty research and student training." A true and correct copy of PAR 19-366 is attached hereto as Exhibit B.

7. As stated in an email I received from Dr. JoAnn Trejo, one of the UCSD leaders of the IRACDA program, the San Diego IRACDA program has had twenty-two continuous years of funding, with four successful competitive grant renewals. SD IRACDA has trained over 134 postdoctoral fellows. All our alumni are employed in science, sixty-five percent have obtained faculty positions at academic institutions, including thirty percent in R1 (research-intensive institutions), twenty-six percent in R2 (teaching and research) institutions, and eight percent in teaching-focused institutions. Almost all our faculty alumni, ninety percent, are in tenured-track positions, and sixty-one percent of faculty have gained extramural funding from various agencies, including the NIH, NSF, USDA, DOD, AHA and National Geographic. A true and correct copy of the email announcing termination of the IRACDA program is attached hereto as Exhibit C.

8. My research examines how the brain changes during pregnancy to enable adaptive parental behaviors. Specifically, I focus on the hypothalamus to understand molecular and physiological shifts that coordinate parental care. This work addresses longstanding questions in neuroendocrinology and behavioral neuroscience and supports NIH's mission to uncover mechanisms of health-related behavior across the lifespan. My interest in this topic grew from years of studying how internal state and context shape social behavior—from fieldwork to molecular systems. Pregnancy is a time of significant changes to the brain and body, driven by hormonal shifts and the need to support a growing fetus. Studying this dynamic period can reveal how the brain adapts, offering insights into neuroplasticity and the impact of biological and environmental factors on brain function. This research is vital for understanding

pregnancy-related mental health issues, like postpartum depression, and can inform better treatments. It also has broader implications for maternal bonding, parenting, and child development, ultimately improving healthcare and well-being for women and families.

9. This diversity-centered training framework was articulated in the application process and was a significant focus of both my proposed mentoring and teaching activities. I was selected through a competitive review based on scientific merit and alignment with the program's dual focus on high-impact research and inclusive pedagogy. The decision to rescind the award—despite its compliance with the original NOFO criteria—has had a direct and detrimental effect on my research progress and my structured career development plan toward academic independence, as I detail below.

10. The IRACDA application required extensive planning over several months. I collaborated with research and teaching mentors, developed a comprehensive training and research plan, and received feedback through multiple rounds of internal and external review. I consulted with my IRACDA Program Coordinators to ensure the project aligned with programmatic goals and refined my application accordingly. The process reflected a high level of scrutiny and rigor consistent with NIH funding standards.

11. I was awarded the IRACDA Fellowship in May 2024 and am currently in the end of my first year of the three-year program. The training timeline includes mentored research, teaching development, and academic career preparation. The sudden cancellation of the program has disrupted that timeline at a critical career transition point.

12. Since the start of the fellowship, I have launched a new line of research examining maternal brain plasticity. I've developed protocols, completed experiments, mentored undergraduate researchers, and presented my work at invited talks at multiple institutions. I have also participated in IRACDA's structured pedagogy training and built relationships with local institutions that served underrepresented groups in STEM, particularly with San Diego State University ("SDSU"). My engagement with this local institution is rooted in a commitment to mentorship, inclusive teaching, and skill-building for students from historically marginalized backgrounds. At SDSU, I have actively participated in the Maximizing Access to Research Careers ("MARC") and the College Assistance Migrant Program ("CASA"). These programs aim to provide support and resources to students from underserved backgrounds, empowering them to succeed in STEM fields.

13. As part of my engagement, I have led multiple workshops that focus on developing research skills, effective communication, and professional development. These workshops were designed to help students gain confidence and improve their ability to present and discuss their research in both academic

and professional settings. Additionally, I have provided valuable feedback on student research talks, helping to refine their communication strategies and enhance the quality of their presentations. Through my involvement in these programs, I've been able to contribute to creating an inclusive academic environment that prioritizes access to education and mentorship for students from historically marginalized groups. I believe that supporting underrepresented groups in STEM is not only essential for social equity but also for the continued advancement of scientific discovery. By fostering a diverse and inclusive community, we can ensure that a wider range of perspectives, experiences, and ideas are brought into the field, which ultimately enriches the scientific process and its outcomes.

14. While my teaching and mentoring at SDSU through the MARC and CASA programs is a significant aspect of my outreach work, it represents only a portion of the broader commitment I've made as a postdoctoral fellow to support equity and inclusion in science. At the "UCSD", I am actively involved in the Jail Outreach Program, whose goal is to teach incarcerated individuals about science, aiming to make scientific knowledge accessible and empowering to all, regardless of background or circumstance. I also mentor undergraduate students in the lab, helping them develop technical skills, confidence, and a deeper understanding of the research process. Additionally, I coordinate science outreach activities for elementary school students in rural communities—bringing hands-on learning experiences to students who might otherwise have limited exposure to STEM fields.

15. This work is ongoing and deeply integrated into my academic career. It is not only driven by a commitment to service but also designed to culminate in scholarly outputs, including publications and future faculty job applications. Any disruption to this fellowship jeopardizes far more than short-term research productivity—it puts at risk a comprehensive effort to broaden participation in science and my long-term academic trajectory.

16. The current grant for UCSD's IRACDA program has a project start date of August 1, 2003 and end date of June 30, 2026. On April 2, 2025, less than a year into my IRACDA fellowship, Kenneth D. Gibbs, Jr., Director of the Division of Training and Workforce Development at the NIGMS sent an email titled "NIGMS Funding Update" to Dr. Joann Trejo, program coordinator of the UCSD IRACDA program stating that the IRACDA program had been "terminated" "due to changes in NIH/HHS priorities." See Exhibit C.

17. Both my lab and I made extensive scientific and logistical plans based on the assumption that I would have two more years of funding through IRACDA. This included designing multi-phase experiments, mentoring commitments, and time allocation for both research and pedagogical training.

The loss of this support now forces a major restructuring of these plans, with consequences for personnel, project feasibility, and timelines.

18. This decision is deeply harmful on multiple levels:

a. **To my career**: The fellowship was designed to bridge me to academic independence. The unexpected loss of fellowship support forces a major shift in my academic career trajectory and jeopardizes my competitiveness for future faculty positions. My long-term goal is to secure a tenure-track faculty position focused on the neural basis of social behavior. The original fellowship was designed to give me financial stability and protected time needed to generate preliminary data, complete publications, and build a competitive research portfolio for the faculty job market within a specific window. Now, with two years of guaranteed stipend support suddenly lost, I will have to accelerate my timeline for applying to faculty positions significantly—by at least a full year. This compressed timeline means I will need to rush key steps in my career development, including the completion of experiments, data analysis, manuscript preparation, and the development of my independent research proposal. As a result, I may go on the job market with fewer completed projects and less mature publications than I had planned, weakening my competitiveness and narrowing the opportunities available to me. In addition, the loss of financial stability will likely require me to divert time toward securing stopgap funding or additional work responsibilities to support myself in the interim. These competing demands will further limit the time I can devote to strengthening my research portfolio at a critical career stage, making the transition to academic independence more difficult and less strategically timed.

b. **To the research**: My project investigates how pregnancy reshapes the maternal brain—a question of both fundamental and translational significance. From a *fundamental* perspective, this research seeks to uncover the basic, underlying mechanisms that govern how pregnancy affects neural circuits, brain structure, and behavior. This involves exploring how hormonal changes, genetic factors, and environmental influences during pregnancy lead to either short-term or long-lasting changes in the maternal brain. Understanding these processes is essential to expanding our knowledge of neuroplasticity and the brain's ability to adapt to physiological states. Furthermore, a deeper understanding of brain-body interactions during pregnancy could lead to improved management of health conditions that involve both brain and bodily functions, such as

stress responses, metabolic health, and immune system changes during this critical period. From a *translational* standpoint (i.e., how this research translates to human-focused clinical research), this research holds significant potential for improving clinical outcomes, especially for women who experience pregnancy-related complications like perinatal mood disorders, postpartum depression, or cognitive changes. By translating basic research into clinical applications, we aim to identify potential biomarkers or therapeutic targets that could mitigate or prevent adverse neurological outcomes in mothers. However, the shortened timeline for this research will force experiments to be conducted in a hurried manner, potentially compromising the depth and rigor of the science. This could limit our ability to fully dissect the intricate molecular and behavioral processes at play, thus affecting both the robustness of the data and its broader applicability.

c. **To the institution and broader field**: UCSD invested in me as a Chancellor's and IRACDA Fellow. My research contributes to NIH priorities in maternal health, brain plasticity, and social behavior. Undermining this work not only wastes invested resources but potentially stalls progress in a vital area of public health.

19. I am seeking to file this declaration under seal because I am concerned about potential repercussions to my career. I fear that disclosure of my name as a participant in this litigation will result in reputational harm, especially given the current climate where individuals have been targeted for expressing principled views on diversity, equity, inclusion, due process, free speech, peaceful protest, or for opposing genocide.

20. I am also concerned that my participation could negatively affect how I am perceived by colleagues, both at my institution and in my broader field. This could impact future collaborations, mentorship opportunities, and the reception of my research. In the current political and institutional climate, we have seen university administrations—including at institutions like Columbia University—fail to protect their own students and faculty from targeted attacks for engaging in peaceful protest or expressing principled views related to free speech, diversity, equity, and inclusion. These precedents raise legitimate concerns that similar punitive or reputational consequences could arise for others, particularly those speaking out on these important issues. I believe that exercising caution in this context is both reasonable and necessary.

21. I also fear that participating publicly could jeopardize my future eligibility for federal research funding. As an early-career scientist, access to such funding is essential to my long-term academic and research goals. Losing these opportunities would significantly disrupt my career trajectory.

22. I have talked to others in similar positions to me who have shared that they also fear participating in this suit or expressed concerns about my participation They have privately expressed concern about participating due to fear of professional backlash and the potential impact on future funding or academic positions. They have also expressed support for my decision to proceed under seal.

I declare under penalty of perjury that the foregoing is true and correct.
Executed this 20th day of April 2025.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF UAW MEMBER 11

I, Delaney K. Sullivan, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am an MD/PhD student in the University of California Los Angeles ("UCLA")-Caltech Medical Scientist Training Program ("MSTP") currently pursuing a PhD in biology at the California Institute of Technology ("Caltech"). I study computational biology, writing software and algorithms for analyzing genomics sequencing data. I was motivated to pursue biology research from a curiosity for science and from wanting to specifically study biomedical sciences after my father passed away from colon cancer.

2. I hold a B.S. in biology and an M.S. in computer science, both from Stanford, and have completed two years of medical school at the David Geffen School of Medicine at UCLA. I am passionate about applying computer science towards solving problems in biology and medicine. I am in my fourth year of the biology PhD program at Caltech.

3. I am a dues-paying member of United Auto Workers ("UAW") Local 2478.

4. My research is in developing new algorithms, methods, software, and tools for analyzing single-cell RNA sequencing data ("RNA-seq data"). RNA-seq data is complex and large (often multiple terabytes) and a lot of it is produced from biology experiments. Methods that efficiently analyze such data while revealing both gene expression and genetic variants or mutations at the single-cell level will enable novel discoveries in biology and medicine, especially in contexts like cancer, where RNA can be abnormal in both sequence and expression. As someone with both a computer science degree and a biology background, I was motivated to take a data-driven approach to understanding complex diseases like cancer given how much data is already available and is being produced daily. My research, which involves studying genetic variation and analyzing massive datasets, aligns with the mission of the

National Institute of Health ("NIH"), National Human Genome Research Institute ("NHGRI"), which specifically seeks to both "maximally leverage the usability and utility of emerging datasets for genomic studies of human health and disease" and "characterize intraindividual genomic variation and understand its role in human disease." A true and correct copy of an NHGRI document announcing these principles is attached as Exhibit A.

5. On April 8, 2024, I applied for the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research ("F31-Diversity"), which was assigned application number 1F31HG014118-01.

6. As described in the program announcement, PA-23-271, The purpose of the F31-Diversty award "is to enhance the diversity of the health-related research workforce by supporting the research training of predoctoral students from diverse backgrounds including those from groups that are underrepresented in the biomedical, behavioral, or clinical research workforce. Through this award program, promising predoctoral students will obtain individualized, mentored research training from outstanding faculty sponsors while conducting well-defined research projects in scientific health-related fields relevant to the missions of the participating NIH Institutes and Centers. The proposed mentored research training is expected to clearly enhance the individual's potential to develop into a productive, independent research scientist." A true and correct copy of the synopsis for PA-23-271 is attached hereto as Exhibit B. The online link to the full listing for PA-23-271 is no longer accessible online.

7. On September 9, 2024, the advisory council met. The role of advisory councils is to meet to discuss applications and advise the NIH Institute (e.g. NHGRI) program director whether an application should advance to the funding stage. The title of the proposal was "k-mer based local uniqueness exploration." This is the name of a novel method I am developing to pick out the parts of genes that distinguish one human being from another human being, or that distinguish a cancer cell from a normal cell. It received an Impact Score: 26, Percentile: 15.0.

8. I chose the F31 diversity because, prior to applying, I was informed, per NHGRI policies, that: (1) NHGRI does not participate in the F30 award (designed for MD-PhD students like me), and (2) the regular F31 would not fund my medical education (only my PhD studies). That left the F31-Diversity award (which I was eligible for given that, in accordance with the NOFO, I am part of a group that is "underrepresented in the biomedical, behavioral, or clinical research workforce") as the only award that would have funded both my medical and PhD studies. With the choice of applying to the F31 (funding PhD-only) vs. F31-diversity, I elected the F31-diversity.

9. It took me considerable effort and around 150 hours in total to assemble the grant application. The final PDF was 50 pages. This effort also took a good chunk of time away from my research. I needed to secure three recommendation letters from people I had worked with in the past, write an extensive research strategy with preliminary data, write an NIH biosketch (which is the NIH variant of a curriculum vitae required as part of the application), and secure a sponsor letter (a document from the Ph.D. advisor stating their means of supporting of me and affirming my qualifications). I needed to communicate back-and-forth between myself, my advisor's lab manager, and the Caltech grants manager (with over a dozen emails exchanged) to ensure the application was in good shape and all necessary forms were complete.

10. On November 22, 2024, I was informed by NHGRI (via email from Temesgen Fufa) that it "has received programmatic concurrence for funding." I interpret this as meaning I received a fundable score, as I was later congratulated via NIH email on January 6, 2025, on my application being "approved for funding". True and correct copies of the November 22 and January 6 emails are attached at Exhibits C and D.

11. As of April 12, 2025, however, I have not received a Notice of Award ("NOA"). I think I should have received an NOA award by now. On an NIH webpage that answers questions about NRSA fellowships, https://www.cancer.gov/grants-training/training/funding/general-fellowships-faq, it says "The time between receipt of an application and funding is approximately 6-9 months."

12. The latest status history message on eRA commons was February 12, 2025, with the note (on page 3 of 4): "Award prepared: refer questions to Grants Management Specialist." A true and correct copy of this message is attached as Exhibit E. eRA Commons is the NIH website that grant applicants log into to check their grant status; the website can be found at https://public.era.nih.gov/commonsplus

13. I have never received any indication that my grant application was in jeopardy or that somehow my grant application was deficient.

14. I have received no specific explanation from NIH why my application has been delayed despite my inquiries.

15. On February 4, 2025, I wrote two NIH officials asking about the status of the NOA for my grant. I shared my understanding that F31 diversity no longer exists – an understanding I had because on that day (February 4, 2025), the grants.gov webpage on the F31-diversity NOFO PA-23-271 was edited with a "closing date" of "Current Closing Date for Applications:" and an "archive date" of Mar 06, 2025 – and my hope that I could be considered and funded through the traditional F31 mechanism. I received

no response to my email. A true and correct copy of this February 4 email is attached as Exhibit F and a true and correct copy of the webpage with the closing date information is attached as Exhibit G.

16. On April 9, 2025, now a year after my submission, I wrote NIH again. I pointed out that my application was successful (as I was congratulated on being "approved for funding" via NIH email on January 6, 2025), and an award had been prepared ("award prepared" was the status indicated on my grant in eRA commons) but that I was never awarded the money. I asked for a written statement in response.

17. The next day, April 10, 2025, the Program Director of NHGRI responded saying that my application is "still pending" and that "NHGRI Grants Management is currently understaffed" and that they would reach out "as soon as an update is available."

18. Based on what other applicants for F30/F31/F31-diversity grants have told me, NIH typically does not take over a year to issue a notice of award about funding with months of silence during the process.

19. The status of my application has caused me much emotional distress and has nearly entirely obliterated my dreams of pursuing an academic career, knowing that I could be treated so unfairly.

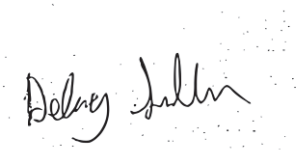
20. The distress could not have come at a worse time: This is my final year of my PhD where I'm already burdened with the dissertation writing process. I have two ongoing projects that I have been unable to complete (one of which was the subject of the grant proposal), in part due to the anxiety of awaiting the news of whether the award would be funded or pulled and not receiving any communication or updates of any kind over the course of multiple months.

21. Now, it is nearly impossible that either project will be published in a peer-reviewed publication before I graduate, leaving me uncertain whether either project will ever be published. Given my graduation timeline (I will graduate no later than the end of this year, as most MSTP students have been imposed with the expectation to graduate in 4 years), I cannot possibly submit another F31 application, because the time from submission to funding takes approximately nine months, after which I will have already graduated.

22. I will suffer both monetary loss and negative professional impact if this award is not funded. The UCLA-Caltech MSTP program provides a $3,500 stipend increase annually for students who receive sufficient extramural funding (such as the amount funded in an F31 award); thus I will not be able to receive this money. Moreover, NIH NRSA awards are important to include on applications to Physician-Scientist Training Program ("PSTP") residency programs. As stated by one article, https://doi.org/10.1172/jci.insight.158467, 67% of PSTP directors in pediatrics programs consider such

awards "very important or fairly important" in terms of decision-making when evaluating applicants for their program; i.e. earning such an award will boost how "competitive" an applicant appears. Thus, it is evident that I will be impacted professionally.

I declare under penalty of perjury that the foregoing is true and correct.
Executed this 18th day of April, 2025.



Delaney K. Sullivan

EXHIBIT A

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Perspective

Strategic vision for improving human health at The Forefront of Genomics

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Check for updates

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Starting with the launch of the Human Genome Project three decades ago, and continuing after its completion in 2003, genomics has progressively come to have a central and catalytic role in basic and translational research. In addition, studies increasingly demonstrate how genomic information can be effectively used in clinical care. In the future, the anticipated advances in technology development, biological insights, and clinical applications (among others) will lead to more widespread integration of genomics into almost all areas of biomedical research, the adoption of genomics into mainstream medical and public-health practices, and an increasing relevance of genomics for everyday life. On behalf of the research community, the National Human Genome Research Institute recently completed a multi-year process of strategic engagement to identify future research priorities and opportunities in human genomics, with an emphasis on health applications. Here we describe the highest-priority elements envisioned for the cutting-edge of human genomics going forward—that is, at 'The Forefront of Genomics'.

Beginning in October 1990, a pioneering group of international researchers began an audacious journey to generate the first map and sequence of the human genome, marking the start of a 13-year odyssey called the Human Genome Project[1–3]. The successful and early completion of the Project in 2003, which included parallel studies of a set of model organism genomes, catalysed enormous progress in genomics research. Leading the signature advances has been a greater than one million-fold reduction in the cost of DNA sequencing[4]. This decrease has allowed the generation of innumerable genome sequences, including hundreds of thousands of human genome sequences (both in research and clinical settings), and the continuous development of assays to identify and characterize functional genomic elements[5,6]. These new tools, together with increasingly sophisticated statistical and computational methods, have enabled researchers to create rich catalogues of human genomic variants[7,8], to gain an ever-deepening understanding of the functional complexities of the human genome[5], and to determine the genomic bases of thousands of human diseases[9,10]. In turn, the past decade has brought the initial realization of genomic medicine[11], as research successes have been converted into powerful tools for use in healthcare, including somatic genome analysis for cancer (enabling development of targeted therapeutic agents)[12], non-invasive prenatal genetic screening[13], and genomics-based tests for a growing set of paediatric conditions and rare disorders[14], among others.

In essence, with growing insights about the structure and function of the human genome and ever-improving laboratory and computational technologies, genomics has become increasingly woven into the fabric of biomedical research, medical practice, and society. The scope, scale, and pace of genomic advances so far were nearly unimaginable when the Human Genome Project began; even today, such advances are yielding scientific and clinical opportunities beyond our initial expectations, with many more anticipated in the next decade.

Embracing its leadership role in genomics, the National Human Genome Research Institute (NHGRI) has developed strategic visions for the field at key inflection points, in particular at the end of the Human Genome Project in 2003[15] and then again at the beginning of the last decade in 2011[16]. These visions outlined the most compelling opportunities for human genomics research, in each case informed by a multi-year engagement process. NHGRI endeavoured to start the new decade with an updated strategic vision for human genomics research. Through a planning process that involved more than 50 events (such as dedicated workshops, conference sessions, and webinars) over the past two years (see http://genome.gov/genomics2020), the institute collected input from a large number of stakeholders, with the resulting input catalogued and synthesized using the framework depicted in Fig. 1.

Unlike the past, this round of strategic planning was greatly influenced by the now widely disseminated nature of genomics across biomedicine. A representative glimpse into this historic phenomenon is illustrated in Fig. 2. During the Human Genome Project, NHGRI was the primary funder of human genomics research at the US National Institutes of Health (NIH), but the past two decades have brought a greater than tenfold increase in the relative fraction of funding coming from other parts of the NIH.

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Fig. 1 | Four-area strategic framework at The Forefront of Genomics. Together, the indicated progressive and interrelated areas serve to organize the major elements in the strategic vision described here.

The planning process continually encountered the realities associated with the broad and extensive use of genomics and the impracticality of being comprehensive, which together served to focus attention on the most cutting-edge opportunities in human genomics. This experience affirmed NHGRI's recently rearticulated role in providing genomics leadership at the NIH, embodied by our newly conceived organizational mantra: 'The Forefront of Genomics'. We ultimately linked this mantra to the strategic planning process to help guide the formulation of input. From the ensuing discussions, it became apparent that responsible stewardship is a central aspect of being at (and pushing forward) The Forefront of Genomics, specifically in the four major areas detailed in Fig. 1, Boxes 1–4, and below.

Principles and values for human genomics

As genomics has matured as a discipline, the field has embraced a growing set of fundamental principles and values that together serve as a guiding compass for the research efforts—some of these emerged organically within the field, whereas others have been adopted from the broader scientific community. The growing complexities of human genomics and its many applications (especially in medicine) at The Forefront of Genomics make it imperative to reaffirm, sharpen, and even extend these tenets, such as those highlighted in Box 1.

Many of these principles and values have been informed by the recognized area of genomics that focuses on ethical, legal, and social implications (ELSI) research[17], which was established at the beginning of the Human Genome Project to ensure that the eugenics movement and other misuses of genetics are not repeated. ELSI research has since grown to encompass a broad portfolio of studies that examine issues at the interface of genomics and society, the results of which have informed policies and laws related to genetic discrimination, intellectual property, data sharing, and informed consent[18]. Similar efforts seek to ensure that the benefits of genomics are available to all members of society[19]. Genomics, like other scientific fields, must reckon with systematic injustices and biases, fully mindful of their importance for health equity. In the future, ELSI research needs to focus on aspects of genomic medicine implementation that present challenging questions about legal boundaries, study governance, data control, privacy, and consent. Complex societal issues must also be studied, including the expanded application of genomics in non-medical realms (for example, ancestry testing, law enforcement, and genetics-based marketing of consumer goods)[20]. Finally, ELSI research should also examine the implications of studying genetic associations with bio-behavioural traits (such as intelligence, sexual behaviour, social status, and educational attainment)[21] and of a future in which machine learning and artificial intelligence are used to adapt risk communication and clinical decisions based on analysing an individual's genome sequence[22].

Robust foundation for genomics

Genomics is now routinely and broadly used throughout biomedical research, with widespread reliance on a robust foundation for facilitating genomic advances. The foundation's integrity depends on several key elements, including infrastructure, resources, and dynamic areas of technology development and research. Sustaining and improving that foundation are key responsibilities at The Forefront of Genomics,

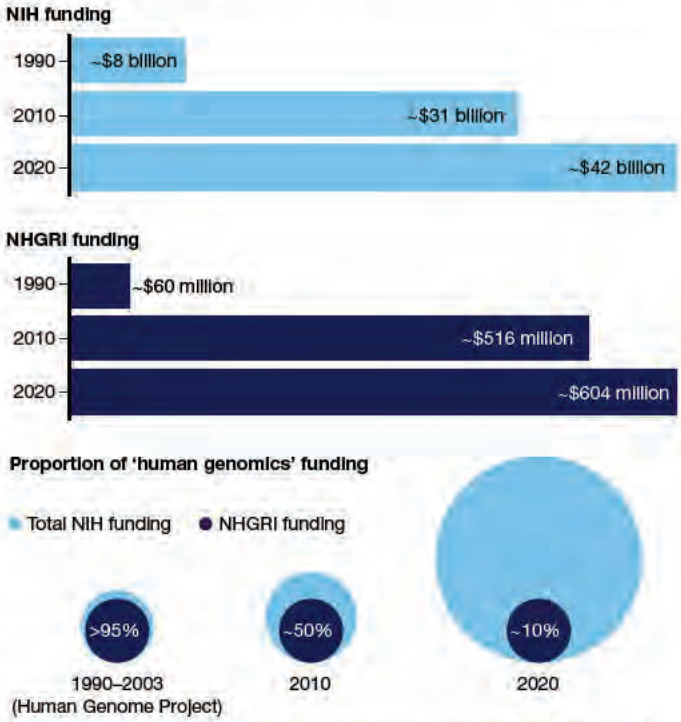


Fig. 2 | Funding trends of NIH and NHGRI over the past 30 years. The total funding levels for the NIH (top) and NHGRI (middle) are indicated for 1990, 2010, and 2020. Also shown (bottom) is the relative proportion of funds supporting human genomics research provided by NHGRI versus all of the NIH for the three corresponding time intervals (as derived from queries of the internal NIH Research, Condition, and Disease Categorization database for funds assigned to the 'human genome' category). During the 30-year period when the NHGRI budget increased roughly tenfold (middle), the proportion of total NIH funding for human genomics research actually increased more markedly, from less than 5% during the Human Genome Project to around 90% at the beginning of the current decade (bottom). In essence, these trends reflect a leveraging of NHGRI's funds that increased NIH's overall human genomics research funding by greater than tenfold.

A1249

Box 1

Guiding principles and values for human genomics

- **Maintain an overarching focus on using genomics to understand biology, to enhance knowledge about disease, and to improve human health** — genomics is now foundational across the entire continuum of biomedical research, from deciphering fundamental principles of biology to translating that knowledge into disease prevention and medical advances.
- **Strive for global diversity in all aspects of genomics research, committing to the systematic inclusion of ancestrally diverse and underrepresented individuals in major genomic studies** — attention to diversity in genomics research is both socially just and scientifically essential, which includes meaningful, sustained partnerships with diverse communities in the design and implementation of research studies, the propagation of research findings, and the development and use of new technologies.
- **Maximize the usability of genomics for all members of the public, including the ability to access genomics in healthcare** — engagement, inclusion, and understanding the needs of diverse and medically underserved groups are required to ensure that all members of society benefit equitably from genomic advances, with particular attention given to the equitable use of genomics in healthcare that avoids exacerbating and strives towards reducing health disparities.
- **Champion a diverse genomics workforce** — the promise of genomics cannot be fully achieved without attracting, developing, and retaining a diverse workforce, which includes individuals from groups that are currently underrepresented in the genomics enterprise.
- **Provide a conceptual research framing that consistently examines the role of both genomic and non-genomic contributors to health and disease** — routinely considering the importance of social and environmental factors that influence human health (and the interactions among those components and genomics) will be important for the comprehensive understanding of most human diseases.

- **Promote robust and consistently applied standards in genomics research** — the use of carefully defined standards (for example, those for generating, analysing, storing, and sharing data) has benefited genomics in numerous ways, and this must include appropriate privacy and data-security protections for those participating in genomics research.
- **Embrace the interdisciplinary and team-oriented nature of genomics research** — starting with the Human Genome Project, some of the most challenging genomics endeavours have benefited from the creation and management of large, interdisciplinary research collaborations.
- **Adhere to the highest expectations and requirements related to open science, responsible data sharing, and rigor and reproducibility in genomics research** — the genomics enterprise has a well-respected history of leading in these areas, and that commitment must be built upon and continually reaffirmed.
- **Pursue advances in genomics as part of a vibrant global community of genomics researchers and funders** — the challenges in genomics require the collective energies and creativity of a collaborative international ecosystem that includes partnerships among researchers, funders, and other stakeholders from academia, government, and the commercial sector.

the major elements of which are highlighted in Box 2 and detailed in corresponding paragraphs below.

Genome structure and function

The past two decades have brought a greater than million-fold reduction in the cost of DNA sequencing[23] along with marked advances in technologies for functional genomics[6,24,25] (that is, the study of how elements in the genome contribute to biological processes). Further opportunities are anticipated as the generation and analysis of genomic data become even faster, cheaper, and more accurate. Near-term expectations include enhanced capabilities for generating high-quality and complete (for example, telomere-to-telomere and phased) genome sequences[26,27], and continued refinement and enhanced utilization of a human genome reference sequence(s) that increasingly reflects human variation and diversity on a global scale[28] and that serves as a substrate for genome annotation[29]. Technologies for generating DNA sequence and other data types (for example, transcriptomic data, epigenetic data, and functional readouts of DNA sequences) need to be enabled at orders-of-magnitude lower costs, at single-cell resolution, at distinct spatial locations within tissues, and longitudinally over time[30–32]. These genomic data should be integrated with other multi-omic data (for example, proteomes, metabolomes, lipidomes, and/or microbiomes) in sophisticated ways, including methods that collect many data types from a single sample[32]. Transformative approaches will become increasingly vital for assimilating, sharing, and analysing these complex and heterogeneous data types[33] and must expand to include the integration of environmental, lifestyle, clinical, and other phenotypic data. These capabilities should be incorporated into browsers, portals, and visualization tools for use by a broadening community of researchers and clinicians.

Genome sequences have now been generated for more than 1,000 vertebrate species and are increasingly accompanied by multi-species annotations[34]. Understanding natural genomic variation, the conservation of genomic elements, and the rapid evolutionary changes in genomic regions associated with specific traits is crucial for attaining a comprehensive view of genome structure and function. The study of a wide range of organisms continues to be instrumental for determining the effect of genomic variation on biological processes and phenotypes, providing insights about the interplay of genomic variants and environmental pressures[35] and the relevance of putative pathogenic variants identified in clinical studies[36]. It is essential that the generation of high-quality multi-species genomic data is accompanied by community-accepted standards for data, metadata, and data interoperability. New methods would allow for integrating functional data from diverse species with human data and visualizing increasingly complex comparative genomic datasets. Continued progress in this area would move the field closer to the long-term aspirational goal of understanding the evolutionary history of every base in the human genome.

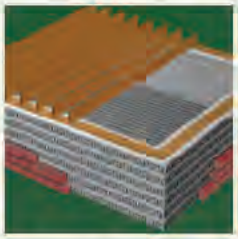
Genomic data science

All major genomics breakthroughs so far have been accompanied by the development of ground-breaking statistical and computational methods. Accordingly, continued innovations in both traditional and advanced methods (including machine learning and artificial intelligence) should be prioritized[37]. These approaches must be considered from the early stages of study planning and data collection in ways that complement and enhance, rather than inhibit, technical progress. Furthermore, the biomedical research community requires accurate, curated, accessible, secure, and interoperable genomic data

Case: 25-16 Case: 1:25-cv-10787-BEM Document: 49-2 Date Filed: 04/25/2025 Page: 11 of 45 ID: 6756750

Box 2

Sustaining and improving a robust foundation for genomics



Genome structure and function
- Enable the routine generation and analysis of increasingly complex genomic data
- Use evolutionary and comparative genomic data to maximize understanding of genome function

Genomic data science
- Develop new methods and build sustainable data resources for genomics research
- Ensure facile storing, sharing, and computing on large genomic datasets
- Develop integrated knowledgebases and informatics methods for genomic medicine

Genomics and society
- Understand the interrelationships between genomics and the social and environmental factors that influence human health
- Empower people to make well-informed decisions about genomic data and develop data-stewardship systems that reinforce their choices
- Increase the genomic literacy of all sectors of society

Training and genomics workforce development
- Ensure that the next generation of genomic scientists are sufficiently trained in data science
- Train healthcare providers to integrate genomics into the clinical workflow
- Foster a diverse genomics workforce

repositories and informatics platforms that benefit all populations. Approaches for improving the efficiency of such resources include the use of shared storage and computing infrastructure, the adoption of common data-management processes, and the development of increasingly automated data-curation methods[38]. Carefully considered funding strategies must be designed to support these methods and resources, including a global, multi-funder model that ensures their development, enhancements, and long-term sustainability[39].

Recent progress has brought substantial transformations in how the petabytes of genomic data being generated each year are assimilated and analysed, including the emergence of cloud-based and federated approaches. Effective and efficient management of increasingly complex genomic datasets requires addressing challenges with these emerging approaches as well as innovations in the use of hardware, algorithms, software, standards, and platforms[40]. Current barriers include the lack of interoperable genomic data resources (which limits downstream access, integration, and analyses) and the absence of controlled and consistently adopted data and metadata vocabularies and ontologies[41,42]. User-friendly systems that capture metadata in a scalable, intelligent, and cost-effective manner and that allow for intuitive data visualizations are essential. Ever-improving routines and guidelines should be formulated to continue and even enhance responsible data sharing, requiring the collective efforts of researchers, funders, and publishers alike; similar attention should focus on ensuring the use of FAIR (findable, accessible, interoperable, and reusable) data standards and the reproducibility of data analyses[38]. Innovations in technology and policy must be integrated to develop data-stewardship models that ensure open science and reduce data-access burdens to advance research, including the use of optimally balanced and ethically sound approaches for respecting participant preferences and consent as well as engaging communities. Such developments should be done in an open-source culture to build consensus and enable the development, maintenance, and use of best-in-class tools, pipelines, and platforms that can be applied to all datasets.

The full integration of genomics into medical practice will require informatics and data-science advances that effectively connect the growing body of genomic knowledge to clinical decision-making. To make genomic information readily accessible and broadly useful to clinicians, user-friendly electronic health record-based clinical decision support tools must be created to interact with a variety of clinical data from electronic health record and other data systems (for example, laboratory, pharmacy, and radiology) as well as non-computable reports, such as those provided as portable document format (PDF) files[43,44]. These efforts require well-curated, highly integrated, and up-to-date knowledgebases that connect genomic information to clinical characteristics, other phenotypic data, and information on family health history[45]. Reliable risk-stratification and prevention algorithms, including polygenic risk scores (PRSs)[46], must be developed and should incorporate both common and rare genomic variants from a broad range of population subgroups, phenotypic data, and environmental information into the risk modelling[47]. Such algorithms should be evaluated both for their validity across many populations and for their effect on patient outcomes and subsequent healthcare utilization. Finally, it will be important to evaluate new genomics-oriented clinical decision support tools to ensure that they are acceptable to practitioners across the spectrum of clinical disciplines.

Genomics and society

Understanding the role of genomics in human health requires knowledge and insights about how social, environmental, and genomic risk factors interact to produce health outcomes[48,49] (Box 1). Given that such interactions are, in general, poorly understood, it is crucial that studies of genomic risk (particularly of common, complex diseases) account for the social and environmental factors that influence health and disease[50]. These factors must be properly described, measured, and incorporated in genomic studies[51]. Optimal implementation of genomic medicine will require an understanding of how the intersectional aspects of people's social and political identities influence the ways in which populations are described in research. Such knowledge will, in turn, provide clarity about the interrelationships among these many influences on health and disease.

People want to be able to make well-informed decisions about their genomic data, leading to the engagement efforts in initiatives such as the UK Biobank[52] and the 'All of Us' Research Program[53]. Partnering with communities and individuals is fundamental to engaging participants in such large-scale research. Genomics researchers must incorporate models and methods of community engagement in their experimental design. Such studies must be appropriately adapted for different cultures and designed to reduce inequities and healthcare disparities; they must also be accompanied by effective information dissemination[54]. An unrelenting focus on the optimal ways to conduct research in partnership with data stakeholders and communities would ensure the identification of the key issues and values influencing peoples' choices about the provision of personal data for research[55,56]. Data-stewardship infrastructures that integrate appropriate policies, technologies[57], and governance and legal frameworks must be developed and assessed to ensure alignment between communities' and individuals' decisions about their data and the practices of researchers and clinicians.

To fully realize the benefits of genomic advances, a working understanding of the basic concepts of genomics will be important for science educators[58], healthcare professionals[59], policymakers, and the public[60]. Several educational strategies will inevitably be required to enhance the genomic literacy of these heterogeneous groups, which points to the need for innovative approaches that are shared, assessed, and improved over time[58]. A growing evidence base shows that increasing the understanding

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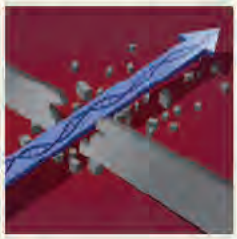
Box 3

Breaking down barriers that impede progress in genomics



Laboratory and computational technologies

- Transform the study of the functional consequences of genomic variation by enhancing the scale of DNA synthesis and editing
- Maximally leverage the usability and utility of emerging datasets for genomic studies of human health and disease

Biological insights

- Establish the means to determine the functional consequences of genomic variants affecting human health and disease
- Characterize intraindividual genomic variation and understand its role in human disease

Implementation science

- Develop and assess strategies for implementing the use of genomic information in clinical care
- Test public health approaches for implementing population-wide genomic screening

of key genomics concepts and applications attracts students to careers in genomics[61], assists with the use of genomics for addressing health disparities[62], and facilitates the uptake of genomic medicine[63]. Curricula for enhancing genomic literacy must be designed to be accessible, effective, and scalable for use in the full range of settings where genomics education is provided—including primary and secondary schools, science museums, and informal science-education venues. Researchers and educators must also disseminate information about both the science of genomics as well as the key ethical and societal implications of genomics[64].

Training and genomics workforce development

Appropriate skills in data science and data stewardship are now prerequisites for becoming a genomics researcher[65]. Furthermore, given the ever-expanding use of genomics in basic, translational, social, behavioural, and clinical research, a greater number of scientists will require fundamental data-science skills that are appropriate for the genomic applications being used[66]. Establishing and maintaining data-science competencies for conducting genomics research requires a series of interrelated educational and training efforts[67], including the recruitment of many data scientists into genomics and the reciprocal exchange of expertise between genomics researchers and data scientists.

Moving into healthcare, providers must be poised to manage questions from patients who receive genomic information, including that from direct-to-consumer (DTC) testing, and this applies to the full spectrum of medical professionals (including nurses, pharmacists, physicians, and other clinicians)[68]. Education modules tailored to specific user groups should be designed to adapt rapidly to advances in genomics and data-science technologies; these should be available on demand and, where appropriate, integrated into existing clinical systems[69]. Research on the methodologies for train-the-trainer approaches, implementation of standards and competency-based education, and strategies for enhancing genomic literacy among all healthcare providers at all career stages[70] should also be pursued. The involvement of patients, caregivers, educators, professional organizations[71], and accreditation boards will be crucial to ensure success. Importantly, cross-training in relevant aspects of genomics must also be available for specialists working in or around healthcare systems, including (but not limited to) those involved in health services research, health economics, law, bioethics, and social and behavioural sciences.

In both research and clinical settings, the global genomics workforce—as with the general biomedical research workforce—falls considerably short of reflecting the diversity of the world's population (a vivid example of this is seen in the United States[72]), which limits the opportunity of those systematically excluded to bring their unique ideas to scientific and clinical research[73]. To attain a diverse genomics workforce, new strategies and programs to reduce impediments to career opportunities in genomics are required, as are creative approaches to promote workforce diversity, leadership in the field, and inclusion practices. Efforts must intentionally include women, underrepresented racial and ethnic groups, disadvantaged populations, and individuals with disabilities. Initiatives should not focus exclusively on early-stage recruitment; instead, they must also include incentives to recruit and retain a diverse workforce at all career stages[74] as well as new approaches for cultivating the next generation of genomics practitioners.

Breaking down barriers in genomics

Genomics has benefited enormously from the proactive identification of major obstacles impeding progress and the subsequent focused efforts to break down those barriers. Prototypic successes include the call for a '[US]$1,000 human genome sequence' after completion of the Human Genome Project[15] and proposed actions to facilitate genomic medicine implementation in 2011[16]; in these cases, both the risks of failure and the benefits of success were high. Once again, breaking down barriers, as highlighted in Box 3 and detailed below, would accelerate progress and create new research and clinical opportunities at The Forefront of Genomics.

Laboratory and computational technologies

Advances in DNA synthesis and genome editing allow the field of genomics to progress from largely observational ('reading DNA') to more experimental ('writing' and 'editing' DNA) approaches. Enabling true 'synthetic genomics' (that is, the synthesis, modification, and perturbation of nucleic acid sequences at any scale) will allow for more powerful experimental testing of hypotheses about genome variation and function and improve opportunities for linking genotypes to phenotypes[75]. Genome editing is increasingly being used for practical applications in medicine (such as in gene therapy[76]), biotechnology, and agriculture. Despite recent triumphs, however, the current approaches are limited in their ability to interrogate genome function at the pathway or network level and to study important phenomena, such as gene regulation and chromosome organization and mechanics, that involve factors that act across large chromosomal (or genomic) distances. Furthermore, radically new capabilities for understanding how the full complement of genomic variation within any individual genome contributes to phenotype should be pursued. Innovative approaches for generating nucleic acid molecules with defined sequences and of any size, coupled with technologies that allow for the concurrent and large-scale perturbation of many genes or simultaneous examination of multiple genomic variants, would be transformative. These advances would benefit from the development of methods to introduce large synthetic constructs into mammalian cells.

In recent years, large human genomics projects have often relied on data generated as part of existing research studies, and emerging approaches involve developing biobanks and organized cohorts[77–79]. Meanwhile, DTC companies are generating substantial amounts of genomic data, and those efforts are rapidly being eclipsed by that being generated in the clinical care setting[80]. Properly leveraged, these DTC and clinical data offer opportunities for genomics-based studies at unprecedented scales; however, these data are often heavily fragmented, siloed, and mostly outside the purview of genomics researchers and their typical funders[81]. Eliminating the barriers to accessing these sources of data for conducting research is essential, but this will require resolving issues

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Box 4

Compelling genomics research projects in biomedicine

- Acquire an increasingly comprehensive view of the roles and relationships of genes and regulatory elements in pathways and networks
- Determine the genetic architecture of most human diseases and traits
- Design studies that include diverse ancestral populations to enable scientific discoveries and genomic medicine for all
- Understand how the use of genomics can influence concepts of health, disease, responsibility, identity, family, and community
- Extend multi-omic studies of human disease and health into clinical settings
- Design and use genomic learning healthcare systems for knowledge generation and improvements in clinical care

related to governance, policy infrastructure, and informatics and workflow solutions. Approaches are needed to mitigate the resulting gaps, limitations, and biases within this highly distributed data environment (for example, with regards to population diversity, data-collection strategies, data standards, and data privacy), all while addressing concerns of the patients, participants, and groups. These challenges must be addressed globally[81] (Box 1), so as to accommodate differences in healthcare systems and views about data privacy. In addition, the healthcare stakeholders should take advantage of opportunities offered by genomics, thereby enabling virtuous-cycle routes between genomic learning healthcare systems and basic genomics research[82] (Fig. 3).

Biological insights

Despite progress in identifying genomic variants that cause monogenic traits or are statistically associated with complex phenotypes, determining the connection of specific variants to phenotypes remains challenging[83]. Systematic approaches, including tactics that connect high-throughput molecular readouts of functional genomic assays to organismal phenotypes, are required to establish the phenotypic consequences of all genomic variants—individually and in combination—in a cell-type context across the life span[84]. Progress in this area requires global collaboration[85], advances in integrating several data types and performing perturbation assays, protein localization or interaction experiments, and animal models, as well as resources cataloguing information about the fitness consequences of de novo mutations and the clinical relevance of genomic variants[83]. Because it is not possible to directly test every variant in all cell types and states, developmental stages, and disease processes, new data-collection strategies and analytical approaches are needed that can generalize and adapt predictions to new contexts, handle sparse data, and prioritize variants for experimental follow-up.

Recent advances have led to a greater appreciation of the extent of mosaicism—that is, genomic variation among cells (both somatic and germline) within an individual. Although there have been remarkable advances in understanding the somatic genomic changes encountered in cancer[86], there is a paucity of detailed knowledge about other effects of mosaicism beyond a few well-studied examples[87]. Important areas of future research include investigating the prevalence and extent of different forms of mosaic variation in both nuclear and mitochondrial DNA, the mechanisms that generate mosaicism, and the roles of mosaicism in physiology and human disease. Such efforts might reveal whether this form of genomic variation contributes to variable penetrance and expressivity, comprises a form of genetic epistasis, explains any currently undiagnosed diseases or sporadic cases (or apparent phenocopies) of known inherited diseases[9], or can inform the design of therapies for genetic diseases. Single-cell genomic technologies have extended knowledge about the functional effects of mosaicism in different experimental systems[88,89], with the next challenge being to translate such single-cell understanding to in vivo settings. The development of laboratory and clinical approaches to readily detect genomic mosaicism at high spatial and temporal resolutions, especially in non-invasive ways (for example, requiring minimal amounts of tissue), would be catalytic.

Implementation science

A crucial barrier to using genomics for improving health and preventing disease is the lack of clinical uptake of proven genomic interventions. Implementation science approaches are needed to identify the most effective methods and strategies for facilitating the use of evidence-based genomic applications, most notably pharmacogenomics-based selection of medications[90], in routine clinical care. New experimental designs, such as genotype-specific participant recruitment[91] or integration of patient-provided genomic data[92] (captured during previous healthcare encounters or from DTC sources), should be explored for their potential to speed adoption and limit costs. The effectiveness of centralized resources for genomic referrals (for example, genomic medicine specialists, consult services[93,94], and centres of excellence in undiagnosed diseases—akin to transplantation centres or cancer centres) should be explored as potential steppingstones to the more generalized uptake of genomics in clinical care. Strategies for deploying the limited workforce of highly trained genetics or genomics specialists (for example, systematic referral networks or telemedicine or telecounseling) should also be evaluated for their effectiveness at increasing the availability of services broadly—as opposed to being limited to select, highly specialized centres.

Universal newborn genetic screening may represent the most visible and successful approach to population-based identification of serious and treatable inherited conditions, but population screening across the lifespan for other genetic conditions is less widely accepted. Standard public health screening approaches for the US Centers for Disease Control and Prevention Tier 1 conditions[95,96] (for example, Lynch syndrome, hereditary breast and ovarian cancer, and familial hypercholesterolemia) identify people at risk through blood relatives of affected individuals (referred to as 'cascade testing' by geneticists[97]). Implementation research methods, coupled with effective science communication, are primed for optimizing approaches to engage individuals in genetic testing for these disorders, in addition to other emerging indications, such as genetic predisposition to adverse drug effects (pharmacogenomics), carrier testing of prospective parents, use of PRSs in disease detection and prevention[46], and genomic indicators (for example, gene-expression and epigenetic patterns) of exposure to infectious pathogens[98] and other environmental agents.

Compelling genomics research projects

The field of genomics has routinely benefited from a willingness to articulate ambitious—often audacious—research efforts that aim to address questions and acquire knowledge that (at the time) may seem out of reach. Such boldness has served to stimulate interest in emerging opportunities, recruit new expertise, galvanize international collaborations involving several funders, and propel the field forward. Although by no means comprehensive, the areas highlighted in Box 4 and detailed below illustrate the broadening range of compelling research projects that are ripe for pursuit at The Forefront of Genomics.

Advances in understanding gene regulation[5,24], the myriad functional roles of RNA[99], and the multi-dimensional nature of the nucleome[100]—coupled with the use of single-cell genomic approaches[30,31] and anticipated

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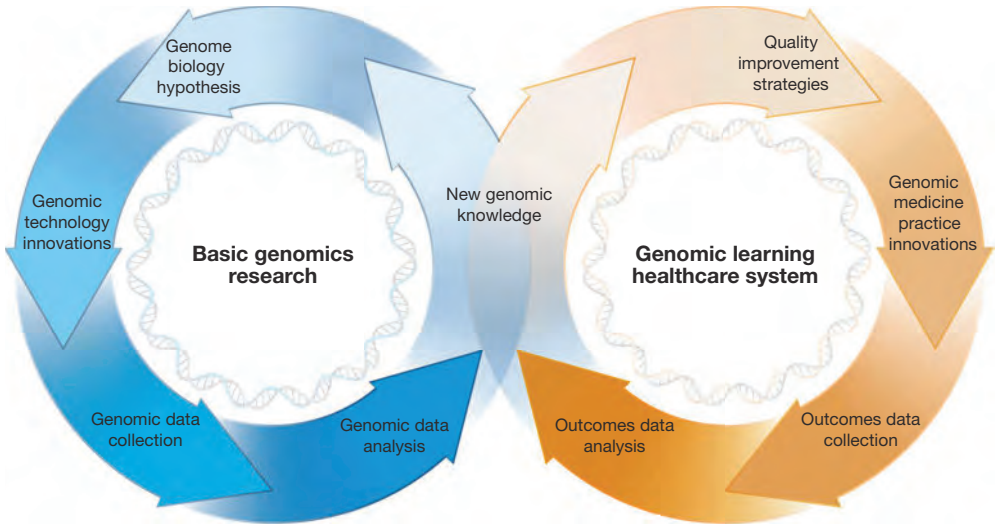

Fig. 3 | Virtuous cycles in human genomics research and clinical care. As human genomics has matured as a discipline, productive and connected virtuous cycles of activity have emerged, each self-improving with successive rounds of new advances. The cycle on the left reflects basic genomics research, in which technology innovations spur the collection and analysis of genomics research data, often yielding new knowledge and further hypotheses for testing. The cycle on the right reflects a genomic learning healthcare system, in which the implementation of new genomic medicine practice innovations allows for the collection and analysis of outcomes data, often yielding new genomic knowledge and additional genomics-based strategies for improving the quality of clinical care. Note that the new knowledge emerging from either the left or the right cycle has the potential to feed into the other, creating opportunities for 'bench to bedside' and 'bedside back to bench' progressions[82]—both of which are expected to grow in the coming decade.

new technological and computational capabilities for analysing genomic datasets and variants—provide an unprecedented opportunity to decipher the individual and combined roles of each gene and regulatory element. This must start with establishing the function of each human gene, including the phenotypic effects of human gene knockouts. Because genes and regulatory elements do not function in isolation, it is imperative to build robust experimental and computational models that deduce causal relationships and accurately predict cellular and organismal phenotypes using pathway and network models[101,102]. Analysis methods must address functional redundancy as well as the nearly boundless experimental space and complexity, including cell states and fates, temporal relationships, environmental conditions, and individual genetic background.

Building on the recent successes in unravelling the genetic underpinnings of rare and undiagnosed diseases[9], the field is poised to gain a more comprehensive understanding of the genetic architecture of all human diseases and traits[10,85]. However, myriad complexities can be anticipated. For example, any given genomic variant(s) may affect more than one disease or trait (that is, pleiotropy); can confer disease risk or reduce it; and can act additively, synergistically, and/or through intermediates. New methods to analyse data that account for human diversity[103], coupled with a growing clarity about genotype–phenotype relationships, must be developed to deduce associations and interactions among genomic variants and environmental factors, improve estimates of penetrance and expressivity, and enhance the clinical utility of genomic information for predicting risk, prognosis, treatment response, and, ultimately, clinical outcomes.

Prioritizing the generation of genomic and corresponding phenotypic data from ancestrally diverse participants is a scientific imperative[104] and essential for achieving equitable benefits from genomic advances[105] (Box 1). However, this is an area in which genomics has repeatedly fallen short[19], leading to missed opportunities for understanding genome structure and function, identifying variants conferring risk for common diseases[106], and implementing genomic medicine for the benefit of all[107–109]. Ideally, studies should be designed for different groups, adapted for local sensibilities and situations, and consistent in capturing key information beyond participants' ancestry (for example, the physical and social environments in which they live and receive healthcare[110]). Leveraging new insights from studies of diverse populations will require the development of robust methods for identifying signatures of natural selection, performing genotype imputation, mapping disease loci, characterizing genomic variant pathogenicity, and calculating PRSs[103,109]. Success in these efforts will yield a more-complete understanding of how the human genome functions in different environments and offer benefit to those participating in genomics research. Attaining the level of population diversity that will truly benefit all people requires bold scientific and community-based leadership, dedicated resources from funders, highly committed researchers, and effective partnerships that earn the trust of diverse groups of participants and their communities.

As genomics has grown in medicine and society, its potential to influence people's actions has also expanded. Increasingly, genomics has affected concepts of health, disease, responsibility, family, identity, and community, raising many important and changing questions. When and how is genomic information shared and communicated within families[111]? Will the identification of a strong genetic risk for a disease change a person's perception of their health or others' perception of that person? As some genetic risks are more common in certain identifiable populations, what role does group affiliation have in how risk is communicated and perceived, including potential group stigmatization? Research that catalogues, analyses, and measures the effect of genomics on individuals, families, and communities is important to provide a more informed context to avoid future misrepresentations, misunderstandings, and misuses of genomics[54]. Finally, researchers must appreciate how their own backgrounds and experiences shape their interpretations of genomic data[112].

Extending genomics research in clinical settings beyond DNA sequence to include other multi-omic data, together with clinical variables and outcomes, would advance understanding of disease onset and progression and may also prove important for drug-discovery efforts[113,114]. This would require tissue- and cell-specific analyses that integrate these data, providing real-time snapshots of biological and disease processes. For clinical applicability and adoption, these high-dimensional, multi-omic data should be integrated with clinical decision support tools and electronic health records. Ultimately, such efforts could reveal important relationships among genomic, environmental, and behavioural variation and facilitate a transition of

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Box 5

Bold predictions for human genomics by 2030

Some of the most impressive genomics achievements, when viewed in retrospect, could hardly have been imagined ten years earlier. Here are ten bold predictions for human genomics that might come true by 2030. Although most are unlikely to be fully attained, achieving one or more of these would require individuals to strive for something that currently seems out of reach. These predictions were crafted to be both inspirational and aspirational in nature, provoking discussions about what might be possible at The Forefront of Genomics in the coming decade.

1. Generating and analysing a complete human genome sequence will be routine for any research laboratory, becoming as straightforward as carrying out a DNA purification.
2. The biological function(s) of every human gene will be known; for non-coding elements in the human genome, such knowledge will be the rule rather than the exception.
3. The general features of the epigenetic landscape and transcriptional output will be routinely incorporated into predictive models of the effect of genotype on phenotype.
4. Research in human genomics will have moved beyond population descriptors based on historic social constructs such as race.
5. Studies that involve analyses of genome sequences and associated phenotypic information for millions of human participants will be regularly featured at school science fairs.
6. The regular use of genomic information will have transitioned from boutique to mainstream in all clinical settings, making genomic testing as routine as complete blood counts.
7. The clinical relevance of all encountered genomic variants will be readily predictable, rendering the diagnostic designation 'variant of uncertain significance (VUS)' obsolete.
8. An individual's complete genome sequence along with informative annotations will, if desired, be securely and readily accessible on their smartphone.
9. Individuals from ancestrally diverse backgrounds will benefit equitably from advances in human genomics.
10. Breakthrough discoveries will lead to curative therapies involving genomic modifications for dozens of genetic diseases.

the use of genomics in medicine from diagnosing and treating disease to maintaining health.

Sharp barriers between research and clinical care obstruct the virtuous cycle of moving scientific discoveries rapidly into clinical care and bringing clinical observations back to the research setting[82] (Fig. 3). Learning healthcare systems—in which real-time data on outcomes of healthcare delivery are accessed and used to enhance clinical practice—can lead to continuous care improvement, but only if the barriers between research and clinical care are reduced[115]. For example, offering genome sequencing to all members of a healthcare system, performed in conjunction with research and participant engagement and provided in real time[81], could help to assess the clinical utility of genomic information and may allow providers to improve disease diagnosis and management. System-wide implementation of such an experiment requires not only extensive patient and provider education, sophisticated informatics capabilities, and genomics-based clinical decision support, but also the development and evaluation of data security and privacy protections to ensure patient confidentiality[116]. Patients should be engaged in the design of such systems and informed at entry to them (and periodically thereafter), so as to be fully aware of the nature of the ongoing research with their clinical data and the goals and potential risks of their participation[117]. Extending such studies across many healthcare systems should reveal common challenges and solutions[118,119], thereby enhancing the learning healthcare model for genomic medicine more broadly (Fig. 3).

Concluding thoughts

The dawn of genomics featured the launch of the Human Genome Project in October 1990[1]. Three decades later, the field has seen stunning technological advances and high-profile programmatic successes, which in turn have led to the widespread infusion of genomic methods and approaches across the life sciences and, increasingly, into medicine and society.

NHGRI has for the third time[15,16] since the Human Genome Project undergone an extensive horizon-scanning process to capture, synthesize, and articulate the most compelling strategic opportunities for the next phase of genomics—with particular attention to elements that are most relevant to human health. The now near-ubiquitous nature of genomics (including in the complex healthcare ecosystem) presented practical challenges for attaining a holistic assessment of the field. Another reality was that the NHGRI investment in genomics has now been multiplied many-fold by the seeding of human genomics throughout the broader research community. These changes reflect a continued maturation of both the field (in general) and NHGRI (more specifically), nicely aligning with the institute's evolving leadership role at The Forefront of Genomics.

Embracing that role, NHGRI formulated the strategic vision described here, which provides an optimistic outlook that the successes in human genomics over the past three decades will be amplified in the coming decade. Many of the details about what is needed to fulfil the promise of genomics have now come into focus. Major unsolved problems remain—among them determining the role for the vast majority of functional elements in the human genome (especially those outside of protein-coding regions), understanding the full spectrum of genomic variation (especially that implicated in human disease), developing data-science capabilities (especially those that keep pace with data generation), and improving healthcare through the implementation of genomic medicine (especially in the areas of prevention, diagnosis, and therapeutic development). The new decade also brings research questions related to the societal implications of genomics, including those related to social inequities, pointing to the continued importance of investigating the ethical, legal, and social issues related to genomics. But now more than ever, solutions to these problems seem to be within striking distance. Towards that end (and with the characteristic spirit of genomics audacity), we offer ten bold predictions of what might be realized in human genomics by 2030 (Box 5).

The strategic vision articulated here was crafted on behalf of the field of human genomics and emphasizes broad strategic goals as opposed to implementation tactics. The realization of these goals will require further planning in conjunction with the collective creativity, energies, and resources of the global community of scientists, funders, and research participants. NHGRI has taken some initial steps to implement this vision, although these will inevitably need to be adapted as advances occur and circumstances change. Indeed, the final words of this strategic vision were formulated as the world moved urgently to deal with the coronavirus disease 2019 (COVID-19) pandemic (see below), providing a vivid reminder of the need to be nimble and the importance of nurturing all parts of the research continuum—from basic to translational to clinical—for protecting public health and advancing medical science.

Despite the seismic changes seen in genomics since the inception of the field, the fundamental sense of curiosity, marvel, and purpose associated with genome science seems to be timeless. In concluding NHGRI's previous strategic vision[16]—published just under a decade ago—the then-envisioned opportunities and challenges were provided with "… a continuing sense of wonder, a continuing need for urgency, a continuing desire to balance ambition with reality, and a continuing responsibility

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to protect individuals while maximizing the societal benefits of genomics…." With the 2020 strategic vision described here providing a thoughtful guide and with enduring feelings of wonder, urgency, ambition, and social consciousness providing unfettered momentum, we are ready to embark on the next exciting phase of the human genomics journey.

Epilogue: COVID-19 and genomics

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged as a global threat to public health at the end of the multi-year process that generated the above strategic vision. Nonetheless, the COVID-19 pandemic provides a potent lesson about how a tiny string of nucleic acids can wreak global havoc on humankind. Understanding the mechanisms involved in the transmission of the virus, viral invasion and clearance, as well as the highly variable and at times disastrous physiological responses to infection, are fertile grounds for genomics research. Genomics rapidly assumed crucial roles in COVID-19 research and clinical care in areas such as (1) the deployment of DNA- and RNA-sequencing technologies for diagnostics, tracking of viral isolates, and environmental monitoring; (2) the use of synthetic nucleic acid technologies for studying SARS-CoV-2 virulence and facilitating vaccine development; (3) the examination of how human genomic variation influences infectivity, disease severity, vaccine efficacy, and treatment response; (4) the adherence to principles and values related to open science, data sharing, and consortia-based collaborations; and (5) the provision of genomic data science tools to study COVID-19 pathophysiology. The growing adoption of genomic approaches and technologies into myriad aspects of the global response to the COVID-19 pandemic serves as another important and highly visible example of the integral and vital nature of genomics in modern research and medicine.

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Competing interests The authors declare no competing interests.

Additional information
Correspondence and requests for materials should be addressed to E.D.G.
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PA-23-271

Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)

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Funding Opportunity Number:	PA-23-271	**Posted Date:**	Sep 12, 2023
Funding Opportunity Title:	Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)	**Last Updated Date:**	Feb 21, 2025
		Original Closing Date for Applications:	Sep 07, 2025
		Current Closing Date for Applications:	Feb 21, 2025
		Archive Date:	Feb 22, 2025
Opportunity Category:	Discretionary	**Estimated Total Program Funding:**	
Opportunity Category Explanation:		**Award Ceiling:**	$
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Funding Instrument Type:	Grant
Category of Funding Activity:	Education Environment Food and Nutrition Health Income Security and Social Services
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93.286 -- Discovery and Applied Research for Technological Innovations to Improve Human Health
93.307 -- Minority Health and Health Disparities Research
93.361 -- Nursing Research
93.398 -- Cancer Research Manpower
93.837 -- Cardiovascular Diseases Research
93.838 -- Lung Diseases Research
93.839 -- Blood Diseases and Resources Research
93.840 -- Translation and Implementation Science Research for Heart, Lung, Blood Diseases, and Sleep Disorders
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serving Institutions; Historically Black Colleges and Universities (HBCUs); Indian/Native American Tribal Governments (Other than Federally Recognized); Non-domestic (non-U.S.) Entities (Foreign Organizations); Regional Organizations; Tribally Controlled Colleges and Universities (TCCUs) ; U.S. Territory or Possession.

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EXHIBIT C

Gmail

Delaney Sullivan <delaney.lin@gmail.com>

A1266

RE: Inquiry about F31 NOA

1 message

Walters, Angela (NIH/NHGRI) [E] <angela.walters@nih.gov> Mon, Jan 6, 2025 at 4:44 AM
To: "Sullivan, Delaney K." <dksulliv@caltech.edu>

Good morning,

I sent the JIT request out this morning. Once that information is received, I can begin to process the award. It must be submitted in eRA commons by the sponsored programs office. I put a submission date of January 10th, but if you need more time, please don't stress about the date. I know many people are still on holiday leave and it make take some time to process. Please let me know if you have any questions or concerns.

I hope you have a wonderful new years as well and congratulations on being approved for funding.

Angela

Angela Walters

NHGRI Grant's Management Specialist

National Human Genome Research Insititute

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Phone: (301) 402-0750

Email: angela.walters@nih.gov

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A1267

From: Sullivan, Delaney K. <dksulliv@caltech.edu>
Sent: Friday, January 3, 2025 11:02 AM
To: Walters, Angela (NIH/NHGRI) [E] <angela.walters@nih.gov>
Subject: [EXTERNAL] Inquiry about F31 NOA

Hello,

I was emailed that my grant (1F31HG014118-01) received NHGRI concurrence for funding. I'm wondering what the status of the NOA is, when will I receive an update regarding it, and will the update be emailed directly to me or will it appear on my eRA commons?

Thanks and hope you had a wonderful New Years,

Delaney K. Sullivan

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EXHIBIT D

A1269

Outlook

1F31HG014118-01

From Fufa, Temesgen (NIH/NHGRI) [E] <temesgen.fufa@nih.gov>
Date Fri 11/22/2024 12:22 PM
To Sullivan, Delaney K. (Medical Student) <DSullivan@mednet.ucla.edu>; dksulliv@caltech.edu <dksulliv@caltech.edu>
Cc jenny.mercado@caltech.edu <jenny.mercado@caltech.edu>

Caution: External sender from outside our organization.
Proceed with caution with regard to links and attachments.

Report Suspicious

Dear Delaney,

Your grant application (1F31HG014118-01) has received programmatic concurrence for funding. You should be hearing from our grants management staff soon if you have not already. It is our intention that the application will be funded. Please note, however, that this email is not an official notification of NHGRI funding. The official notification of funding will only be provided through the issuance of the Notice of Award (NOA). Please feel free to reach out to Ms. Angela Walters (E-mail: waltersar@mail.nih.gov), the grants management specialist assigned to your application for any questions related to the issuance of the NOA.

I am requesting that you provide additional information addressing the following concerns identified by the review panel, as outlined in the summary statement, including but not limited to:

- **The research plan is missing details about the core algorithm, how the snRNA-seq data would be integrated in Aim 3, and anticipated challenges impact on feasibility.**
- **COMMITTEE BUDGET RECOMMENDATIONS: Reviewers noted that less than 50% of the requested award period will be devoted to graduate research training for this dual degree applicant.**

Please have your Authorized Organizational Representative submit the requested information/responses to me via email.

Best regards,
Temesgen
--
Temesgen D. Fufa, Ph.D. | he/him/his

Case: 25-1611 Document: 00118350953 Page: 510 Date Filed: 10/09/2025 Entry ID: 6756750

A1270

Program Director
Division of Genome Sciences
National Human Genome Research Institute
The National Institutes of Health

6700B Rockledge Drive, Rm 3130
Bethesda, Maryland 20817 USA
E-mail: temesgen.fufa@nih.gov
Phone: (301) 480-2280
https://genome.gov

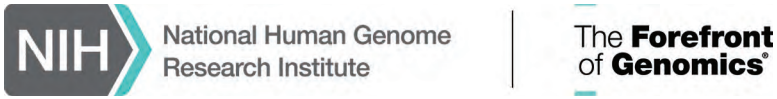

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EXHIBIT E

A1272

Case: 25-1611 Document: 00118350953 Page: 513 Date Filed: 10/09/2025 Entry ID: 6756750

GRANTFLDR

Contacts

Administration: Scientific Review Officer (SRO)
Name: Jurata, Linda Wagner
Phone: (301) 496-8032
Email: linda.jurata@nih.gov

Administration: Grants Management Specialist (GMS)
Name: Walters, Angela
Phone: (301) 402-0750
Email: angela.walters@nih.gov

Administration: Program Official (PO)
Name: Fufa, TEMESGEN D
Phone: (301) 480-2280
Email: temesgen.fufa@nih.gov

Latest Update

Application Source: Grants.gov
Opportunity Number: [PA-23-271] - Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)

Status Information

1F31HG014118-01

Status
Pending administrative review. Refer any questions to Program Official or Grants Management Specialist.

Project Title
k-mer based local uniqueness exploration

PI Name
Sullivan, Delaney Kalcey

NIH Appl. ID
11071524

Application ID
1F31HG014118-01

Status

Status
Pending administrative review. Refer any questions to Program Official or Grants Management Specialist.

Last Status Update Date
02/19/2025

PI Name
Sullivan, Delaney Kalcey

Institution Name
CALIFORNIA INSTITUTE OF TECHNOLOGY
School Name
DIVISION OF BIOLOGY AND BIOLOGICAL ENGINEERING
School Category
SCHOOLS OF ARTS AND SCIENCES
Division Name
NONE
Department Name
NONE

NIH Appl. ID
11071524

Proposal Receipt Date
04/08/2024

Proposal Title
k-mer based local uniqueness exploration

A1273

Project Period Begin Date
09/01/2024

Current Award Notice Date

Project Period End Date

Application Source
Grants.gov

eApplication Status
Submission Complete

Opportunity Number
[PA-23-271] - Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)

Other Relevant Documents

e-Application

Summary Statement

Just In Time 01/06/2025 Times Revised(1)

eSubmission Cover Letter

eSubmission-PHS Assignment Request Form

Additions for Review

Document Event Log

No data available.

Review

Application	Study Section	Advisory Council

eRA Service Desk

Hours: Monday-Friday, 7:00 AM-8:00 PM EDT/EST

Web: https://www.era.nih.gov/need-help

Toll-free: 866-504-9552

Phone: 301-402-7469

Contact initiated outside of business hours via Web or voice mail will be returned the next business day.

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Award Document Number: FHG014118A

FSR Accepted Code: N

Snap Indicator Code:

Impact Score: 26

Percentile: 15.0

For information about next steps: Click here

Early Stage Investigator Eligible:

New Investigator Eligible:

Eligible for FFATA Reporting: Yes

Scientific Review Group: ZRG1 F08-L (20)

Council Meeting Date (YYYY/MM): 2024/10

Meeting Date: 06/27/2024

Meeting Time: 10:00

Study Roster: View Meeting Roster

(AC)

Meeting Date: 09/09/2024

Meeting Time: 09:00

Institute/Center Assignment

Institute or Center	Assignment Date
NATIONAL HUMAN GENOME RESEARCH INSTITUTE (Primary)	04/08/2024
NATIONAL HUMAN GENOME RESEARCH INSTITUTE (Primary)	04/19/2024

Status History

Effect Date	Status Message
02/12/2025	Award prepared: refer questions to Grants Management Specialist.
11/12/2024	Pending administrative review. Refer any questions to Program Official or Grants Management Specialist.

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Effect Date	Status Message
07/02/2024	Scientific Review Group review completed. Refer any questions to Program Official.
04/24/2024	Scientific Review Group review pending. Refer any questions to the Scientific Review Administrator.
04/08/2024	Application entered into system

Reference Letter(s)

This list shows Reference Letters associated with this particular Application. Principal Investigator can see a list of all Reference Letters within Personal Profile - Reference Letters section on eRA Commons

Referee Name	Organization/Affiliation	Department	EMail	Submitted Date
Dawson, David	UCLA	Pathology and Laboratory Medicine	DDAWSON@MEDNET.UCLA.EDU	04/03/2024
Liefwalker, Dan	Oregon State University	Biochemistry and Biophysics	DAN.LIEFWALKER@OREGONSTATE.EDU	04/03/2024
Li, Yulin	Houston Methodist Research Institute	Neal Cancer Center	YLI@HOUSTONMETHODIST.ORG	04/03/2024

A1275

Case: 25-1611 Document: 00118350953 Page: 516 Date Filed: 10/09/2025 Entry ID: 6756750

EXHIBIT F

A1277

Gmail

Delaney Sullivan <delaney.lin@gmail.com>

F31HG014118-01 status?

1 message

Delaney Sullivan <delaneyk.sullivan@gmail.com> Tue, Feb 4, 2025 at 2:55 PM
To: angela.walters@nih.gov, temesgen.fufa@nih.gov

Hi,

Just wondering about the status of NOA for the grant.
As you know, the F31 diversity will no longer exist, and it would be great if my application can be considered and funded under the traditional mechanism, as I believe my qualifications are the same either way.

Look forward to hearing from you,
Delaney

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EXHIBIT G

An official website of the United States government Here's how you know

GRANTS.GOV℠

MENU

VIEW GRANT OPPORTUNITY

PA-23-271

Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)

Department of Health and Human Services

National Institutes of Health

Apply

Subscribe

SYNOPSIS | VERSION HISTORY | RELATED DOCUMENTS | PACKAGE

Version History

Click on Version Name to view previous versions of this grant opportunity. Modifications from the previous version are highlighted with a light gray background. For more information on versions, see Online Help.

Synopsis History:

Version	Modification Description	Updated Date
Synopsis 4	Closed	Feb 21, 2025
Synopsis 3	updated close date	Feb 11, 2025
Synopsis 2	updated close date	Feb 04, 2025
Synopsis 1		Sep 12, 2023

A1279

Case: 25-1611 Document: 00118350953 Page: 520 Date Filed: 10/09/2025 Entry ID: 6756750

DISPLAYING: Synopsis 2

General Information

Document Type:	Grants Notice
Funding Opportunity Number:	PA-23-271
Funding Opportunity Title:	Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)
Opportunity Category:	Discretionary
Opportunity Category Explanation:	
Funding Instrument Type:	Grant
Category of Funding Activity:	Education Environment Food and Nutrition Health Income Security and Social Services

Version:	Synopsis 2
Posted Date:	Sep 12, 2023
Last Updated Date:	Feb 04, 2025
Original Closing Date for Applications:	
Current Closing Date for Applications:	Feb 04, 2025
Archive Date:	Mar 06, 2025
Estimated Total Program Funding:	
Award Ceiling:	
Award Floor:	

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Category Explanation:	
Expected Number of Awards:	
Assistance Listings:	93.113 -- Environmental Health 93.121 -- Oral Diseases and Disorders Research 93.172 -- Human Genome Research 93.173 -- Research Related to Deafness and Communication Disorders 93.213 -- Research and Training in Complementary and Integrative Health 93.233 -- National Center on Sleep Disorders Research 93.242 -- Mental Health Research Grants 93.273 -- Alcohol Research Programs 93.279 -- Drug Abuse and Addiction Research Programs 93.286 -- Discovery and Applied Research for Technological Innovations to Improve Human Health 93.307 -- Minority Health and Health Disparities Research 93.361 -- Nursing Research 93.398 -- Cancer Research Manpower 93.837 -- Cardiovascular Diseases Research 93.838 -- Lung Diseases Research

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93.839 -- Blood Diseases and Resources Research
93.840 -- Translation and Implementation Science Research for Heart, Lung, Blood Diseases, and Sleep Disorders
93.846 -- Arthritis, Musculoskeletal and Skin Diseases Research
93.847 -- Diabetes, Digestive, and Kidney Diseases Extramural Research
93.853 -- Extramural Research Programs in the Neurosciences and Neurological Disorders
93.855 -- Allergy and Infectious Diseases Research
93.859 -- Biomedical Research and Research Training
93.865 -- Child Health and Human Development Extramural Research
93.866 -- Aging Research
93.867 -- Vision Research
93.879 -- Medical Library Assistance

Cost Sharing or Matching Requirement: No

Eligibility

Case: 25-1611 Document: 00118350953 Page: 523 Date Filed: 10/09/2025 Entry ID: 6756750

Eligible Applicants:	Independent school districts County governments Nonprofits that do not have a 501(c)(3) status with the IRS, other than institutions of higher education Small businesses State governments Native American tribal organizations (other than Federally recognized tribal governments) Special district governments Public housing authorities/Indian housing authorities For profit organizations other than small businesses City or township governments Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education Native American tribal governments (Federally recognized) Others (see text field entitled "Additional Information on Eligibility" for clarification) Public and State controlled institutions of higher education Private institutions of higher education
Additional Information on Eligibility:	Other Eligible Applicants include the following: Alaska Native and Native Hawaiian Serving Institutions; Asian American Native American Pacific Islander Serving Institutions (AANAPISISs); Eligible Agencies of the Federal Government; Faith-based or Community-based Organizations; Hispanic-serving Institutions; Historically Black Colleges and Universities (HBCUs); Indian/Native American Tribal Governments (Other than Federally Recognized); Non-domestic (non-U.S.) Entities (Foreign Organizations); Regional Organizations; Tribally Controlled Colleges and Universities (TCCUs) ; U.S. Territory or Possession.

Additional Information

Agency Name:	National Institutes of Health
Description:	Not Available

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Link to Additional Information:	https://grants.nih.gov/grants/guide/pa-files/PA-23-271.html
Grantor Contact Information:	If you have difficulty accessing the full announcement electronically, please contact: NIH Grants Information grantsinfo@nih.gov See Section VII. Agency Contacts within the full opportunity announcement for all other inquires.

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Case: 25-1611 Document: 00118350953 Page: 526 Date Filed: 10/09/2025 Entry ID: 6756750

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF UAW MEMBER 12

I, Amanda Danielle Perez, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. My name is Amanda Danielle Perez and I am a post-doctoral Research Fellow in the School of Public Health at University of California, Berkeley ("Berkeley"). I am in my fifth year of post-doctoral research, which was to be the first step in becoming an interdisciplinary health researcher and faculty member at a research 1 institution. I earned my BA, MA, and PhD from Berkeley in social psychology, and received three years of post-doctoral funding from the school.

2. I am offering this Declaration in my individual capacity and not on behalf of my employer.

3. I am represented by LOCAL 5810—United Auto Workers ("UAW").

4. I am the recipient of a Maximizing Opportunities for Scientific and Academic Independent Careers K99/R00 Postdoctoral Career Transition Award to Promote Diversity ("MOSAIC grant") awarded by the National Institute of Health ("NIH") through the National Institute on Minority Health and Health Disparities ("NIMHD"). The grant award number is K99MD018629, and the Notice of Award ("NOA") for the grant is dated 08/02/2023. A true and correct copy of the NOA is attached hereto as Exhibit A.

5. According to the program announcement, PAR-21-271, at 6, MOSAIC grants are issued by NIH "to enhance workforce diversity by facilitating a timely transition of promising

postdoctoral researchers from diverse backgrounds … from their mentored, postdoctoral research positions to independent, tenure-track or equivalent research-intensive faculty positions." A true and correct copy of the expired PAR is attached hereto as Exhibit B. The MOSAIC program is a specific type of the generic, or parent, K99/R00 award that is designed to increase the participation of scientists from underrepresented backgrounds in academic science, by facilitating the transition to faculty positions for scientists who will promote diversity in academia. The MOSAIC grant provides up to five years of support through two phases, funding up to two years of the MOSAIC scholar's post-doctoral research position (the K99 or "mentored phase") and up to three years of independent research support in a tenure-track faculty position (the R00 or "independent phase"). MOSAIC scholars apply for tenure track positions at institutions in the last year of the mentored phase, and once accepted to a position, the institution at which the scholar will become faculty submits the application for the independent phase. The program announcement for the MOSAIC grant states that receipt of the R00 phase of the award "is contingent on satisfactory progress during the K99 phase and an approved, independent, tenure-track (or equivalent) faculty position. The two award phases are intended to be continuous in time." Id. at 7.

6. MOSAIC grants provide funding both for salary support and research support during the mentored phase. During the independent phase of the award, the MOSAIC grant provides funding for salary and benefits, research costs, and indirect costs reimbursed to the R00 sponsoring institution. The R00 sponsoring institution also commits to providing start-up funds to help the MOSAIC scholar set up their laboratory and some other institutional support. In addition to funding, MOSAIC scholars are provided with mentoring, networking and professional development activities.

7. I initially applied for the MOSAIC grant in October of 2022. The grant is extremely prestigious and competitive, requiring me to go through a rigorous review process before I was selected. The application process was highly demanding, involving several months of preparation, including extensive research, collaboration with colleagues, and multiple revisions to ensure the application met the program's standards. I engaged in detailed discussions with NIH program officers, seeking guidance on aligning my proposal with the program's goals and expectations. The review process itself involved multiple rounds of feedback and evaluation, underscoring the thoroughness and competitiveness of the grant application. My submission

included a diversity statement that emphasized my background as Latina, highlighting how my experiences align with the program's focus on supporting individuals from underrepresented groups in the field of biomedical research science and fostering diversity and inclusion within the field. Id. at 7.

8. My research project focuses on the birth outcome disparities faced by Latinas and the mechanisms driving those disparities. Specifically, my research partner and I propose two novel mechanisms as contributors to poor birth outcomes for Latinas: anticipatory racism threat ("aRT") and area-level racial bias. The mentored phase of my project has involved creating and psychometrically validating the aRT-Latina scale, which is designed to measure anticipatory racism stress among Latina women. The plan was to validate the scale over the next two months, but due to the unexpected funding changes, this process can no longer take place. While the scale has not yet undergone full psychometric testing, it has been developed with expert input and is poised for testing to assess its reliability and validity. Additionally, we are examining the associations between anticipatory racism threat and adverse birth outcomes, including low birth weight and preterm birth, in recent Latina mothers. This project aims to provide a comprehensive understanding of how anticipatory racism may contribute to poor health outcomes for Latinas, offering a unique lens to study maternal health disparities. We are also investigating the role of area-level racial bias, exploring how broader social and environmental factors—such as community-level racial bias—may further exacerbate the effects of individual-level racism and contribute to adverse birth outcomes for Latina women. Ultimately, this work aims to inform interventions and policies that address both individual and systemic factors in the fight to reduce health disparities.

9. My project has important implications for informing the types of interventions likely to ameliorate the longstanding and largely neglected area of Latina birth outcome disparities. By identifying the novel mechanisms of anticipatory racism threat and area-level racial bias, this research sheds light on the unique and intersectional factors contributing to poor birth outcomes among Latina women. Understanding these mechanisms allows for the development of targeted, culturally informed interventions that can directly address the stressors experienced by Latina mothers and the broader structural inequities they face. Furthermore, by creating a validated tool to measure anticipatory racism stress, this project provides a new resource for health professionals, policymakers, and researchers working to reduce health disparities in maternal and

infant health. The findings from this research can guide the creation of community-based programs and healthcare policies that prioritize the needs of Latina women, ultimately improving both prenatal care and maternal health outcomes. In the long term, the work aims to foster systemic change by influencing healthcare systems and social policies to more effectively address the racial and ethnic disparities that continue to impact Latina communities.

10. My NOA states that the project period for the mentored phase of my grant runs from August 2, 2023 until February 28, 2025. Exh. A at 1. The award for my second year of funding was $135,943 (including direct and indirect costs), which was slightly more than the first-year funding. Id. at 3. Second year funding was explicitly made dependent upon "the availability of funds and satisfactory progress of the project." Id. As detailed above, I have made excellent progress on my project.

11. Because my K99 was set to end in February, in the middle of the academic year, my plan has always been to stretch my funding through a No Cost Extension ("NCE") with NIH through June, 2025. This plan was endorsed by my mentors at Berkeley and my NIH contacts. NCEs are routine and can be effectuated without significant administrative hurdle. As my NIH Program Officer explained by email in response to our outreach on this topic in 2023, "Grantees can extend the final budget period once up to 12 months themselves without NIMHD's approval. You can do this online in the last 90 days before your K99 grant period ends." A true and correct copy of the 2023 email from my grant officer is attached hereto as Exhibit C.

12. Once I was within the 90-day window for a NCE, Berkeley submitted the request for an NCE to June 2025 as required. I reached out to my contact at NIH repeatedly in early 2025 to check on the NCE and received no response. NIH also never sent me a revised NOA, which should have been forthcoming, to formally document the NCE.

13. Instead, on April 10, 2025, I received an email from NIH stating that my K99 would end as of April 30, 2025, and my MOSAIC award currently shows up on NIH Reporter with an end date of April 30, 2025. This makes no sense, as it is neither my original end date, nor the No Cost Extension end date. In response to my subsequent inquiries to NIH, I have not received an explanation for why I did not receive the NCE through June. A true and correct copy of the RePorter webpage for my grant is attached hereto as Exhibit D.

14. Based on the assurance from NIH that I would be able to complete a NCE at my discretion, I budgeted my award over the last two years to take a decreased monthly salary. This

would have allowed me to work the three extra months necessary to complete my research and apply for faculty positions in a timely manner. Now I do not have any salary coming in for the next two months, which has left me in a precarious financial position. Without this income, I am unable to cover essential living expenses, including rent and groceries, which has caused significant stress and uncertainty in my personal life. The abrupt change in funding has also severely hindered my ability to finalize my research and meet crucial deadlines for job applications, which were central to my career transition. As a result, I may now be unable to pursue a career in academia, as I need a job immediately to secure financial stability and support myself in the interim.

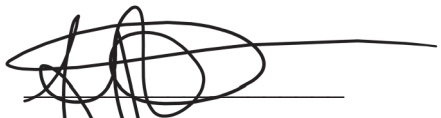
15. In addition to the impacts of an unexpected lack of funding over the next two months to complete the mentored portion of my fellowship, I also have enormous uncertainty for my career because NIH has removed the ability to apply for the R00 independent phase of the MOSAIC program. NIH closed out the most recent PAR for MOSAIC on February 21, 2025, two and a half years before the PAR's expected closing date, and has not issued a new PAR. A true and correct copy of the grant opportunity webpage showing the closing date of the last MOSAIC PAR is attached hereto as Exhibit E.

16. I am in the process of applying for faculty positions, but my interviews have been negatively impacted by my change in funding. Because the MOSAIC R00 opportunity has been removed from NIH's website, I can no longer apply for it. When I applied for faculty positions, I indicated on the applications that I would bring that funding with me; this is no longer the case, which has placed me in a highly disadvantaged position. The loss of this funding not only diminishes my immediate competitiveness for academic roles but also undermines the long-term trajectory of my career. Without this funding, I am left with a significant gap in my financial and research resources, hindering my ability to sustain independent research projects, mentor students, and contribute to my field. The change in funding also impacts my ability to develop a strong research program, which is a critical factor for securing tenure-track faculty positions. As a result, this disruption has delayed my academic career advancement, causing me to reconsider my future in academia and leading to increased uncertainty about securing a permanent position. The long-term ramifications of this funding loss may significantly alter the course of my professional development and my ability to contribute meaningfully to the academic community.

17. This will also have a devastating impact on my research, which is critical in addressing health disparities among Latina women, particularly in maternal health. The loss of funding halts the psychometric validation of the aRT-Latina scale, delaying key data collection and analysis. This setback risks preventing me from generating findings that could inform interventions to improve birth outcomes. Additionally, it disrupts my ability to apply for future funding, stalling both my research progress and my academic career.

18. I am also deeply concerned about the long-term impact on my generation of scientists, especially those from underrepresented groups, who rely on programs like MOSAIC to launch careers dedicated to research and scientific progress. Without the MOSAIC program and similar NIH initiatives, far fewer scientists from diverse backgrounds will have the opportunity to pursue careers in biomedical research. This not only exacerbates the lack of diversity in a field in which many groups are already underrepresented, but also deprives the scientific community of unique perspectives crucial to addressing the core medical issues of our time. The loss of these funding opportunities undermines efforts to create a more inclusive and innovative scientific workforce, ultimately slowing progress in tackling health disparities and advancing solutions to pressing global health challenges.

I declare under penalty of perjury that the foregoing is true and correct.
Executed this 22nd day of April, 2025.



Amanda Danielle Perez

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)

DECLARATION OF UAW MEMBER 13

I, [redacted], pursuant to 28 U.S.C. § 1746, declare as follows:

1. My name is [redacted] and I am a graduate student pursuing my PhD degree at the [redacted] ("[redacted]") Program in Biomedical Sciences and Engineering. I am about to finish the first year of my PhD program, and my studies are funded through a [redacted] fellowship called the Initiative for Maximizing Student Development ("IMSD"). My ultimate goal is to become a professor at a minority serving institution and further drive the field of natural product sciences with aspiring scientists from ethnically diverse backgrounds. I graduated from [redacted] in 2023 with a Bachelor of Science in chemistry where much of my research focused on [redacted] During my undergraduate studies, I found passion for chemistry and how it has the potential to help society and future generations. Since 2022, I have presented my research four times, and on one occasion I was awarded first place for my presentation.

2. I am offering this Declaration in my individual capacity and not on behalf of my employer.

3. I am a dues-paying member of United Auto Workers ("UAW") Local 4811.

4. [redacted]s IMSD fellowship is funded by the National Institutes of Health ("NIH") through the National Institute of General Medical Sciences ("NIGMS"). The grant award number is

[redacted] A true and correct copy of NIH's RePORTER webpage containing information about [redacted]'s grant is attached hereto as Exhibit A.

5. The Notice of Funding Opportunity ("NOFO"), PAR-24-031, is no longer available online. However, PAR-19-037, which is associated with a prior [redacted] IMSD grant, states that the purpose of the IMSD program is to help "develop a diverse pool of scientists earning a Ph.D., who have the skills to successfully transition into careers in the biomedical research workforce" by providing support to research-intensive institutions to develop didactic, research-focused, biomedical training and mentoring programs that "prepare trainees for careers that will have a significant impact on the health-related research needs of the Nation." A true and correct copy of the expired PAR-19-037 is attached hereto as Exhibit B. NIH IMSD grants are awarded directly to higher education institutions.

6. [redacted]'s IMSD program is funded for a ten-year period. *Id.* [redacted] graduate students, however, are provided with full-time support for two years, and new cohorts of IMSD students are selected annually. *See* Ex. A.

7. I began my PhD as an IMSD fellow in September 2024. A true and correct copy of my offer letter for the first year of my IMSD fellowship is attached hereto as Exhibit C. Since beginning at [redacted] I have continued studying chemistry and my research focuses on [redacted]. Specifically, my research explores [redacted] I plan to present my findings in a podcast to increase awareness of [redacted] and its relevance to daily life, and to author an editorial in [redacted] to share with the global scientific community.

8. My research is important because it could contribute to developing strategies for [redacted]. More generally, my research is important because recent years have seen a rise in antimicrobial resistant pathogens, which directly kills about one million people every year. Treatments for these pathogens decrease every few years so new treatment options are extremely important to global health.

9. The current grant for [redacted]s IMSD program began February 1, 2020, and beginning in January 2025, the continuation of the IMSD program at [redacted] became uncertain based on chaos at NIH. In 2024, [redacted] submitted a renewal application for IMSD funding because past funding was scheduled to end on January 31, 2025. The application received a strong score and on

January 7, 2025, the school received an email from Jeremy McIntyre, Program Director within the Division of Training and Workforce Development at NIGMS stating, "I am pleased to inform you that the above referenced grant [redacted] has been approved for funding – congratulations!" The email went on to say that the Notice of Award ("NOA") "should be issued in the coming weeks, and nothing is official until that is received." A true and correct copy of the January 7 email is attached hereto as Exhibit D.

10. As the January 31, 2025 date approached, however, [redacted] never received the NOA that Mr. McIntyre said should be coming, and NIH went silent. On January 31, with no NOA in hand and with several Executive Orders issued that could have implicated the IMSD program, [redacted] was under the impression that NIH funding for IMSD was not coming. On January 31, 2025, less than a year into my IMSD fellowship, I received a revised Notice of Appointment from [redacted] notifying me that my IMSD funding was ending that day. A true and correct copy of the revised Notice of Appointment is attached hereto as Exhibit E.

11. Just three days later, on February 3, 2025, [redacted] was notified that an NOA for continued IMSD funding had been issued by NIH, and I was told that my funding would likely be restored. This was a great relief.

12. Yet on April 2, 2025, Kenneth D. Gibbs, Jr., Director of the Division of Training and Workforce Development at NIGMS sent an email with the subject "NIGMS Funding Update" to the [redacted] Principal Investigator on the award stating "that due to changes in NIH/HHS priorities, the **Initiative for Maximizing Student Development (IMSD)** program has been terminated." A true and correct copy of the April 2, 2025 email is attached hereto as Exhibit F.

13. The chaos caused by NIH's inconsistent communication and ultimate termination of IMSD funding has put my entire financial security at risk. Without this funding, I will have to find other ways to fund my graduate studies, such as teaching assistant ("TA") positions. This will divert my focus from my research because TAing takes a lot of time and effort which will no longer be dedicated to research. I am very aware of how research can be impacted by financial insecurity because I worked multiple jobs throughout my undergraduate career in order to get by; one reason I was so excited about the IMSD funding was because it allowed me to devote all my focus on my passion for researching drug discovery. Additionally, I am expecting my first child, and I was relying on the financial stability that the IMSD fellowship provided me with. If I am forced to TA in addition to parenting and studying, I fear my research will be negatively impacted.

14. I am also very worried about how the termination of IMSD funding will impact other people like me who never would have had the opportunity to discover and explore their passion for science without it. Having mentors nurture my love of chemistry changed my life, and I fear that people who could develop a passion for the sciences like I did won't have the same opportunities. Without the IMSD program and other NIH programs like it, there will be far fewer people who can pursue a career in biomedical research.

15. I don't know if [redacted] is appealing the termination, and even if it does, I do not know the chance of success. I also don't have an understanding of why the IMSD program was cut or how it no longer aligns with agency priorities.

16. I am seeking to file this declaration under seal because I am concerned that my participation in this lawsuit could [redacted]

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 23 day of April, 2025.

[redacted]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-WGY

SUPPLEMENTAL DECLARATION OF SCOTT W. DELANEY, ScD JD MPH

I, Scott W. Delaney, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am offering this Declaration in my individual capacity and not on behalf of my employer.

2. I previously set forth my professional background in my Declaration filed on April 25, 2025, in support of Plaintiffs' Motion for Summary Judgement ("April 25 Declaration;" ECF No. 38, Attachment 27). Briefly, I am an epidemiologist and Research Scientist at the Harvard T.H. Chan School of Public Health (HSPH). I hold a Doctor of Science from HSPH (ScD, 2020) and have conducted epidemiologic research at HSPH in various capacities for eleven years. Throughout my career in epidemiology, I have applied for and received multiple types of grants from NIH either individually or as part of teams. Moreover, my current research activities are supported almost entirely by NIH research grants. Based on these experiences, I am exceedingly familiar with a broad spectrum of grant mechanisms available from NIH.

3. I am also the co-founder of grant-watch.us, a website and series of databases that track terminated NIH grants. This effort began in early March 2025 when I started tracking details of

terminated NIH grants. Together with a colleague, Dr. Noam Ross of rOpenSci, we built the most comprehensive, up-to-date database of specific grants that NIH has prematurely terminated since February 28, 2025. Our database aggregates data from multiple sources, including reports from Principal Investigators (i.e., scientists) whose grants were terminated; news reports; social media; Doge.gov; NIH's X feed; NIH RePORTER; USASpending.gov; and the HHS TAGGS system. Using this database, I previously identified in my April 25 Declaration 755 grants that I believe were terminated for vague policy reasons.

4. Since I compiled the list of terminated grants for my April 25 Declaration, I have learned of more grant terminations. Accordingly, I have updated my count of terminated NIH grants using the same methods outlined in my April 25 Declaration.

5. As of Friday, May 16, 2025, at 10:00 p.m. Eastern Daylight Time, I have identified 813 total grants (i.e., fifty-eight more than the previously reported 755 grants) that NIH has terminated based on vague "policy" assertions. A true and correct list of these fifty-eight additional grants is attached to this Declaration as Exhibit A.

6. Among these additional terminations was Grant Number U24DK137631, which was awarded to researchers at Duke University. The grant, entitled *Interventions that Address Structural Racism to Reduce Kidney Health Disparities Research Coordinating Center*, was part of six-institution (and thus six-grant) consortium organized by the National Institute of Diabetes and Digestive Kidney Diseases (NIDDK) that focused on addressing specific challenges related to kidney health faced by racial minority communities. Other consortium members included researchers at the University of Colorado at Denver (U01DK137272), the University of North Carolina at Chapel Hill (U01DK137262), Northwestern University at Chicago (U01DK137258),

Icahn School of Medicine at Mount Sinai (U01DK137259), and Emory University (U01DK137269). All six of these grants were terminated on April 30, 2025.

7. In addition to investigating these additional fifty-eight grants, I also read carefully the Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction, as well as the Declaration of Jon Lorsch ("Lorsch Declaration"), both of which were filed with the Court on May 12, 2025. The Lorsch Declaration included Exhibit B, which purported to list active National Research Service Award (NRSA) grants. In reference to Exhibit B, Dr. Lorsch declared that "[n]one of these grants were terminated." (Lorsch Declaration, Paragraph 34).

8. I reviewed all grants listed in Exhibit B of the Lorsch Declaration and compared them to evidence I previously collected of terminated grants. Based on my analysis, at least ten NRSA grants listed in the Lorsch Declaration have been and remain terminated, contrary to Dr. Lorsch's assertion. They include, F31AI186480, F31GM155995, F31GM151846, F31HG013889, F31MD018931, T32HL007854, T32GM154636, T32HL105323, T34GM145539, T34GM149430. Eight of these ten NRSA grants were part of programs specifically meant to recruit and train diverse future scientists from underrepresented backgrounds. I believe two other NRSA awards listed in Dr. Lorsch's exhibit—F30AG074618 and F31AG090071—may have been terminated and subsequently reinstated for unknown reasons.

9. More broadly, Defendants contend that, despite terminating some NRSA awards and programs, "NIH is supporting . . . the recruitment of researchers from disadvantaged backgrounds." Defendant's Opposition, ECF No. 66 at 33. To explore this contention, I identified the primary NRSA grant programs from the past year. I focused my analysis on programs in which multiple institutes or centers (ICs) participated. I categorized these programs based on whether they are (1) currently available, such that applicants can apply to them, or (2)

no longer available and / or recently terminated. I further categorized them based on whether they are (or were) meant to support either (1) students and early career researchers from all backgrounds or (2) students and early career researchers exclusively from diverse and / or disadvantaged backgrounds. Unlike the former category, the latter category included programs explicitly designed to diversify the scientific workforce because such programs were only available to applicants from diverse backgrounds. I repeated this process for non-NRSA training awards as well. I have included a true and correct table listing and categorizing these programs as Exhibit B to this Declaration.

10. In sum, I identified eleven NRSA programs from the past year in which multiple ICs participated. Six of these programs are open to all applicants and, thus, are not explicitly designed to support students from diverse backgrounds. All six of these programs are still currently available or forecasted to be available within the next two months. In contrast, five of the eleven programs were explicitly designed to diversify the workforce by targeting only applicants from underrepresented backgrounds. None of these five is currently available or forecasted to be available. Thus, NIH has ended every NRSA program explicitly designed to recruit and support diverse students.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 16 day of May, 2025.

SCOTT W. DELANEY

EXHIBIT A

Award Number	Project Title	Awardee Organization	Termination Date
R21HD107311	An intervention to promote healthy relationships among transgender and gender expansive youth	Seattle Children's Hospital	2025-02-28
R01AI186142	A seek, test, and treat intervention to reduce Chlamydia trachomatis disparities in Black youth living in the deep South	Tulane University of Louisiana	2025-03-20
R01TW012904	Kabawil: Adapting an Intervention to Reduce Intersectional Stigmas among Indigenous Sexual Minority Men and Traditional Healers in Mesoamerica	University of Washington	2025-03-20
P30AI050409-26S1	Center for AIDS Research at Emory University	Emory University	2025-03-21
R01HL168489	A daily diary examination of the influence of intersectional stigma on blood pressure	Columbia University Health Sciences	2025-03-21
R01MD017588-03S1	Promoting Health and Reducing Risk among Hispanic Sexual Minority Youth and their Families	University of Miami Coral Gables	2025-03-21
R01NR019512	Harnessing the power of peer navigation and mHealth to reduce health disparities in Appalachia	Wake Forest University Health Sciences	2025-03-21
U54MD012523-05S1	Center for Health Equity Research (CHER)	University of Illinois at Chicago	2025-03-21
OT2HL161847-01S1	OTA-21-015A Post-Acute Sequelae of SARS-CoV-2 Infection Initiative: NYU Langone Health Clinical Science Core, Data Resource Core, and PASC Biorepository Core	New York University School of Medicine	2025-03-24
P01AI158571-01A1S1	Design and Development of a Pan-betacoronavirus Vaccine	Duke University	2025-03-24
S06GM127983-04S1	Cherokee Nation Native AmericanResearch Center for Health	Cherokee Nation	2025-03-24
S06GM127983-03S1	RAD-X UP NARCH Supplement: A Cherokee Nation Community-Driven Program for Testing and Contact Tracing (Cherokee PROTECT)	Cherokee Nation	2025-03-24
U01AI167892-03S2	HIPC Data Coordinating Center	La Jolla Institute for Immunology	2025-03-24
U19AI171399	AI-driven Structure-enabled Antiviral Platform (ASAP)	Sloan-Kettering Inst Can Research	2025-03-24
U19AI171110	QCRG Pandemic Response Program	University of California, San Francisco	2025-03-24
U19AI171292	RAPIDLY EMERGING ANTIVIRAL DRUG DEVELOPMENT INITIATIVE-AViDD CENTER (READDI-AC)	Univ of North Carolina Chapel Hill	2025-03-24
U19AI171401	Metropolitan AntiViral Drug Accelerator	Hackensack University Medical Center	2025-03-24
U19AI171443	Center for Antiviral Medicines & Pandemic Preparedness (CAMPP)	Scripps Research Institute, The	2025-03-24
U19AI171421	Development of outpatient antiviral cocktails against SARS-CoV-2 and other potential pandemic RNA viruses.	Stanford University	2025-03-24
U24TR001608-06S1	ACTIV-6	Duke University	2025-03-24
U24TR001608-07S1	ACTIV-6	Duke University	2025-03-24
U54EB015408-08S2	Point of Care Technology Research Center in Primary Care	Massachusetts General Hospital	2025-03-24
UM1AI068618-18S1	CoVPN 3008 Multi-Center, Randomized, Efficacy Study of Early vs Deferred Vaccination with COVID-19 mRNA Vaccine in Regions with SARS-CoV-2 Variants of Concern - LC Repository	Fred Hutchinson Cancer Center	2025-03-24
T32GM148406	G-RISE at the University of Puerto Rico Medical Sciences Campus	University of Puerto Rico Med Sciences	2025-04-02
T32GM144924	G-RISE at The University of Mississippi	University of Mississippi	2025-04-02
T32GM144834	Initiative to Maximize Student Diversity at the University of New Mexico Health Sciences Center 2021	University of New Mexico Health Scis Ctr	2025-04-02
K12GM068524	San Diego IRACDA Scholars Program	University of California at San Diego	2025-04-02
T32GM148394	G-RISE at NMSU	New Mexico State University	2025-04-02
F31GM156104	Elucidating the Neuropeptidome Implicated in Crustacean Feeding Processes through Multiplexed Data-Independent Acquisition Mass Spectrometry	University of Wisconsin-Madison	2025-04-02
OT2OD035605	Partnership to Optimize Equity in Maternal and Infant Health	Delta Health Alliance, Inc.	2025-04-07
R01NS123115-02S1	Computational roles of inhibition in human action control	University of Oregon	2025-04-11
F31HG013889	Characterization of adaptive cis-regulatory variation across global populations	Yale University	2025-04-15
R25HG006836	UCSC Research Mentoring Internship Program: An Initiative to Increase Diversity and Inclusion in Genomics Research	University of California Santa Cruz	2025-04-15
R01AI179080	Bacterial and Molecular Determinants of Mycobacterial Impermeability	University of Virginia	2025-04-18
K99DA060266	Early resource scarcity effects on addiction-related behavior: a novel role for retrotransposons.	Georgia State University	2025-04-21
R01AI184122	Role of intestinal microfold (M) cells in creating a hotspot environment for HIV reservoir persistence and reactivation	University of Washington	2025-04-23
R01MH132149-03S1	Promoting Sustained Viral Suppression Through Implementation of an Adapted Evidence-Informed Low-Barrier Care Model in a System of HIV Primary Care Clinics	Northwestern University at Chicago	2025-04-23
R01MH129357-02S1	Anxiety and Interoception Risk for Eating Disorders in Childhood	University of Louisville	2025-04-24
R01EB033916	Robust, Contrast-Free Functional Renal MRI	University of Texas at Austin	2025-04-25

K99NS135649	Computational Methods for Precise Holographic Control and Mapping of Neural Circuits	Columbia Univ New York Morningside	2025-04-28
R01MH126040-03S1	Efficacy of digital cognitive behavior therapy for insomnia for the prevention of perinatal depression	University of California, San Francisco	2025-04-28
F31DK141249	Investigating the roles and dynamics of the endoplasmic reticulum during paligenosis and metaplasia formation	Baylor College of Medicine	2025-04-28
F31MD018931	Hardship and Survival: The Impact of Migration-Related Trauma, Communal Coping, and Social Stressors on the Suicide and Mental Health Outcomes of Latina Immigrant Women	Johns Hopkins University	2025-04-29
DP2MH136495-01S1	Innovations in Personalizing Treatment for Eating Disorders Using Idiographic Methods and the Impact of Personalization on Psychological, Physical, and Sociodemographic Outcomes	University of Louisville	2025-04-30
F31DK138767	Assessing mechanistic relationships of central amygdala neuron activity and glucagon-like peptide-1 receptor agonism	University of Alabama at Birmingham	2025-04-30
R01DK133468-03S1	CyberGut: towards personalized human-microbiome metabolic modeling for precision health and nutrition	Institute for Systems Biology	2025-04-30
U01DK137269	Mitigating the Effects of Structural Racism on Chronic Kidney Disease Disparities among African Americans	Emory University	2025-04-30
U01DK137259	Renal transplant Equity through Partnership and Structural Transformation (REPAST)	Icahn School of Medicine at Mount Sinai	2025-04-30
U01DK137258	Improving access to renal transplantation for Underserved Black Communities	Northwestern University at Chicago	2025-04-30
U01DK137262	CommunityRx – Chronic Kidney Disease (CRx-CKD)" An EMR-integrated community resources referral intervention to address structural racism and kidney health disparities in rural North Carolina	University of North Carolina Chapel Hill	2025-04-30
U01DK137272	NAVIGATE Kidney: A Multi-Level Intervention to Reduce Kidney Health Disparities	University of Colorado Denver	2025-04-30
U24DK137631	Interventions that Address Structural Racism to Reduce Kidney Health Disparities Research Coordinating Center	Duke University	2025-04-30
K99AI173544	Improving phage-based medicine with immunoengineering	University of Pittsburgh at Pittsburgh	2025-05-02
R01AG058066-04S1	Protective Genetic Varients for Alzheimer Disease in the Amish	Case Western Reserve University	2025-05-05
R01MD018459	Elucidating the high and heterogeneous risk of gestational diabetes among Asian Americans: an integrative approach of metabolomics, lifestyles, and social determinants	University of California at Los Angeles	2025-05-05
F31AI186480	From exposure to infection: defining factors modulating the efficiency of influenza A virus infection	Emory University	2025-05-07
K99MH135062	Identifying and manipulating behavioral and neural correlates of contextual learning	Northwestern University at Chicago	2025-05-08
R25LM014208	Building Accessible and Inclusive Paths for Students in Biomedical Informatics and Data Science	University of Pittsburgh at Pittsburgh	2025-05-28

EXHIBIT B

Program[1]	NRSA[2]	Name	Explicitly meant to diversify workforce?	Currently available?[3]
Parent F30	Yes	Ruth L. Kirschstein National Research Service Award Individual Fellowship for Students at Institutions with NIH-Funded Institutional Predoctoral Dual-Degree Training Programs	No	Yes
Parent F30	Yes	Ruth L. Kirschstein National Research Service Award Individual Fellowship for Students at Institutions Without NIH-Funded Institutional Predoctoral Dual-Degree Training Programs	No	Yes
Parent F31	Yes	Ruth L. Kirschstein National Research Service Award Individual Predoctoral Fellowship	No	Yes
Parent F32	Yes	Ruth L. Kirschstein National Research Service Award Individual Postdoctoral Fellowship	No	Yes
Parent T32	Yes	Ruth L. Kirschstein National Research Service Award Institutional Research Training Grant	No	Yes
Parent T35	Yes	Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grant	No	Yes
Diversity F31	Yes	Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research	Yes	No
MARC T34	Yes	Maximizing Access to Research Careers	Yes	No
U-RISE T34	Yes	Undergraduate Research Training Initiative for Student Enhancement	Yes	No
G-RISE T32	Yes	Graduate Research Training Initiative for Student Enhancement	Yes	No
IMSD T32	Yes	Initiative for Maximizing Student Development	Yes	No
Parent K01	No	Mentored Research Scientist Development Award	No	Yes
Parent K08	No	Mentored Clinical Scientist Research Career Development Award	No	Yes
Parent K23	No	Mentored Patient-Oriented Research Career Development Award	No	Yes
Parent K25	No	Mentored Quantitative Research Development Award	No	Yes
Parent K99/R00	No	NIH Pathway to Independence Award	No	Yes
ARC F99/K00	No	Advancing Research Careers Predoctoral to Postdoctoral Transition Award to Promote Diversity	Yes	No
MOSAIC K99/R00	No	Maximizing Opportunities for Scientific and Academic Independent Careers Postdoctoral Career Transition Award to Promote Diversity	Yes	No
MOSAIC UE5	No	Maximizing Opportunities for Scientific and Academic Independent Careers Organizational Research Education Award to Promote Diversity	Yes	No
IRACDA K12	No	Institutional Research and Academic Career Development Awards	Yes	No

[1] For brevity, programs listed above are only those (1) for extramural scientists; (2) focused on student or early career scientist training; and (3) in which multiple institutes or centers (ICs) currently or previously participated. For some programs not listed, only one IC participated. These include NIGMS' Bridges to the Baccalaureate and Bridges to the Doctorate programs, as well as programs in which only NIA or NICHD participated. This table also excludes a wide array of R25 Research Education Programs, many of which were (1) recently terminated or not renewed and (2) meant to support students from underrepresented backgrounds.

[2] NRSA refers to the Ruth L. Kirschstein National Research Service Award program.

[3] Grant mechanisms are listed as "currently available" if either (1) a Program Announcement for the mechanism is active or (2) a Program Announcement for the mechanism is "forecasted" on Grants.gov to be posted as active on or before July 2025.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,

Plaintiffs,

v.

NATIONAL INSTITUES OF HEALTH, et al.,

Defendants.

Case No. 1:25-cv-10787-WGY

SUPPLEMENTAL DECLARATION OF JEREMY M. BERG, PH.D.

I, Jeremy M. Berg, declare as follows:

1. I provide this supplemental declaration in support of Plaintiffs' Motion for Preliminary Injunction (ECF No. 37) and in response to Defendants' Opposition (ECF No. 66), including the Declaration of Jon Lorsch (ECF No. 66-1).

2. I am a former director of the National Institute of General Medical Sciences (NIGMS), one of the twenty-seven National Institutes of Health (NIH). I was Director of NIGMS from 2003-2011. To my knowledge, no terminations of any grants awarded by NIGMS occurred during my time as Director.

3. In his declaration (¶15), Jon Lorsch attaches and explains Exhibit A: a list of grants "related to health disparities in minority populations" which he represents NIH does not presently have any intent to terminate. However, searches of NIH Reporter revealed that MD013352 ("Impact of Navajo Nation Tax on Junk Food") ended in fiscal year 2021 and that MD018641 ("Understanding cancer and comorbidities among American Indian and Alaska Native people") was a two-year R21 award that ended on 4/30/25. In addition, two other awards (MD017106

("Reducing Hypertension among African American Men: A Mobile Stress Management Intervention to Address Health Disparities") and MD018459 ("Elucidating the high and heterogeneous risk of gestational diabetes among Asian Americans: an integrative approach to metabolomics, lifestyles, and social determinants") have unusual records in NIH Reporter with Award Notice Dates of 5/4/25 and Budget End Dates and Project End Dates of 5/5/25. A Project End Date of 5/5/25 would normally indicate that these awards, made very recently, were no longer active. The Project End Dates for the remaining grants included in Exhibit A are as follows: MD015221, 6/30/26; MD019748, 5/31/29; MD018583, 12/31/27; MD014859, 11/30/25; MD018193, 6/30/27; MD014127, 12/31/25; MD015724, 4/30/26; MD012610, 7/31/25; MD016068, 2/28/27; MD015186, 1/31/26; MD020158, 6/30/26; MD014035, 1/31/26; MD013752, 1/31/26; MD014146, 4/30/26; MD013858, 1/31/26; MD016961, 3/31/26; MD014145, 4/30/26; MD016738, 4/30/26; MD019397, 4/30/26; MD015080, 5/31/26; MD019333, 12/31/25; MD019227, 1/31/26.

4. Lorsch notes (¶13) that 431 appeals of grant terminations have been received by NIH. This process is quite opaque, and at this point I have not been able to learn of any appeals that have been successful. In addition, although I have not been able to obtain specific information, colleagues have shared that some requests to appeal have been declined because the Notice of Funding Opportunities to which the applicant responded has been discontinued by the new administration so that there is no remedy for an appeal because there is no available funding opportunity for the specific grant that was terminated.

5. Lorsch states (¶16) that "any funds that are not re-obligated will return to the treasury at the end of the fiscal year consistent with standard practice." While this appears to suggest that returning appropriated funds to the treasury was a common occurrence, my

recollection is that, during my time as NIGMS Director, NIH fully obligated all appropriated funds, such that NIH had final balances of less than $1000 out of an appropriation of nearly $2 billion for each year's appropriated funds.

6. Lorsch states (¶22-26) that NIH has made good progress catching up with the delayed scientific review and advisory council meetings and claims that "NIH anticipates that it will have reviewed 100% of cycle III grant applications" (¶25). However, it is not clear whether 100% of applicants Lorsch refers to includes all applications that were submitted in response to Notices of Funding Opportunities that were active at the time of application submission that were subsequently "expired" – i.e., there are some NOFOs that were active and had applications submitted and assigned out to specific peer reviewers but which were subsequently withdrawn by the new administration. It is not clear how many applications were connected to these withdrawn NOFOs and whether they are included in Lorsch's reporting.[1] It is also not clear what the status is for applications that were submitted in response to active Notices of Funding Opportunities that have been subsequently "expired" with regard to advisory council review. It is possible that such applications may have completed scientific review at study section but then were withdrawn so that they were never made available for advisory council review.

7. In some cases, some applications, specifically F31 applications responding to F31-Diversity funding opportunities were repeatedly reassigned to different study sections and it is not clear if these applications were ever reviewed. My understanding is that for some of these F31-Diversity applications, reviewers asked NIH review staff if such applications could simply be assigned to the Parent funding announcement as the applications are identical except for a single page used to justify eligibility for the diversity program – i.e., remove the one page diversity

[1] https://www.statnews.com/2025/02/07/trump-nih-scraps-prestigious-diversity-program/

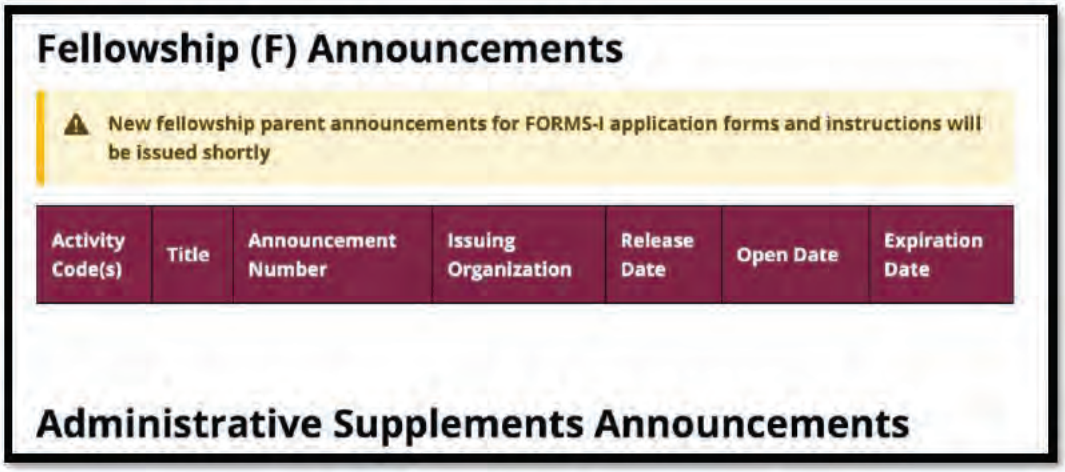
statement for F31-Diversity grants and allow these applications to continue under the standard F31 parent track. However, these reviewers were told that continuing to review the F31-Diversity applications was not possible as a matter of NIH policy.

8. Lorsch states (¶27) that "[f]rom the date of the temporary pause through May 12, 2025, NIH issued 11,362 non-competitive grants. NIH has also issued 1,971 new competitive grants in that same time frame." I was able to essentially reproduce those numbers through searches of the public database NIH Reporter (https://reporter.nih.gov/). To put Lorsch's 2025 numbers in context, I note that from January 28, 2024 through May 12, 2024, NIH issued 14,995 non-competitive grants and 5,557 competitive grants. In the last Presidential transition year (2021), NIH issued 15,691 non-competitive grants and 6,685 competitive grants from January 28 through May 12. Thus, compared to the last Presidential transition year, NIH has issued 72% as many non-competitive grants and 29% as many competitive grants over this same time period.

9. Lorsch states (¶31) that "the parent (NRSA) programs remain active". The parent Notices of Funding Opportunities for the F30[2], F31[3] and F32[4] all had their expiration dates moved up to May 8, 2025 and there were no Notice of Funding Opportunities for the F-series grants active at the time of his declaration as seen from a screen shot from May 13 from the page Lorsch cites in ¶32.

[2] https://grants.nih.gov/grants/guide/pa-files/PA-23-260.html
[3] https://grants.nih.gov/grants/guide/pa-files/PA-23-272.html
[4] https://grants.nih.gov/grants/guide/pa-files/PA-23-262.html

This page has now been updated with a comment that forms will be issued shortly.



However, no Notice of Funding Opportunity has yet appeared and NIH appears to be missing its own target dates. These delays are harmful as graduate students, both early in graduate school or later in graduate school and in the process of searching for postdoctoral fellowship opportunities, may be required to make career decisions based on the current uncertainty.

10. Also included and analyzed (¶34) in the Lorsch Declaration was Exhibit B with a list of 5,172 active NRSA grants.[5] I have performed an analysis of the grants in Lorsch Decl.

[5] The list includes 148 entries from Harvard which, based on recent reports of wide-ranging grant terminations at Harvard University, may in fact have been terminated. *See* https://www.bostonglobe.com/2025/05/16/metro/harvard-trump-administration-grant-terminations/

Exhibit B and my analysis is attached to this declaration as **Exhibit A**. This analysis reveals that 25% of these awards are expected to end by 9/30/2025 with an additional 33% expected to end by 9/30/26. Furthermore, an additional 5% of the grants are at risk for being terminated in fiscal year 2026 as they were awarded in response to a NOFO with a substantial diversity focus and require a non-competitive renewal award for continuation in fiscal year 2027. Finally, it is noted that NIH is making new and competitive renewal awards at a rate that is only 18% of the average rate for the same period in the five previous fiscal years. Taken together, these observations suggests that the level of NRSA funding will drop dramatically if present policies are continued.

11. I have been tracking the amount of the NIH appropriation remaining to be committed and the time remaining in the fiscal year. A recent analysis is attached as **Exhibit B**. The conclusion from this analysis is that, in order to fully allocate the funds appropriated for this fiscal year, NIH must commit more than $27 B appropriated funds from May 1st through September 30th. Such a pace is has essentially never occurred over any month period over the past decade (and likely ever).

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on this 19th day of May, 2025, in Gibsonia, PA.

Jeremy M. Berg, Ph.D.
Former Director (2003-2011)
National Institute of General Medical Sciences
National Institutes of Health

EXHIBIT A

respond to 5087 distinct grants with 74 having multiple records in the pdf. These all or essentially a
competitive renewal, on non-competitive renewal awards and a supplement to that award (identifia

rs available, we can search the NIH Reporter database to recover the full records for these grants i
rtunity used to obtain each award.

grants (F31DE033887, F31AR082294, F31HL163924, TL4GM118986, F31AG077880) were not fo
nt searches revealed that the first four grants ended on 9/30/24, 5/31/24, 8/1/24, and 6/30/24. The
oject end date of 5/24/25 but is not listed as an active grant.

nt numbers were found among active grants on May 17, 2025.

rter database for Active grants with these grant numbers and Activity codes (F30, F31, F32, FM1,
25 records. This is slightly higher than 5172, presumably due to capturing some additional awards
upplements. The sources of this difference could be identified with more analysis but, again, the di
work.

ements focused on increasing diversity in the biomedical workforce

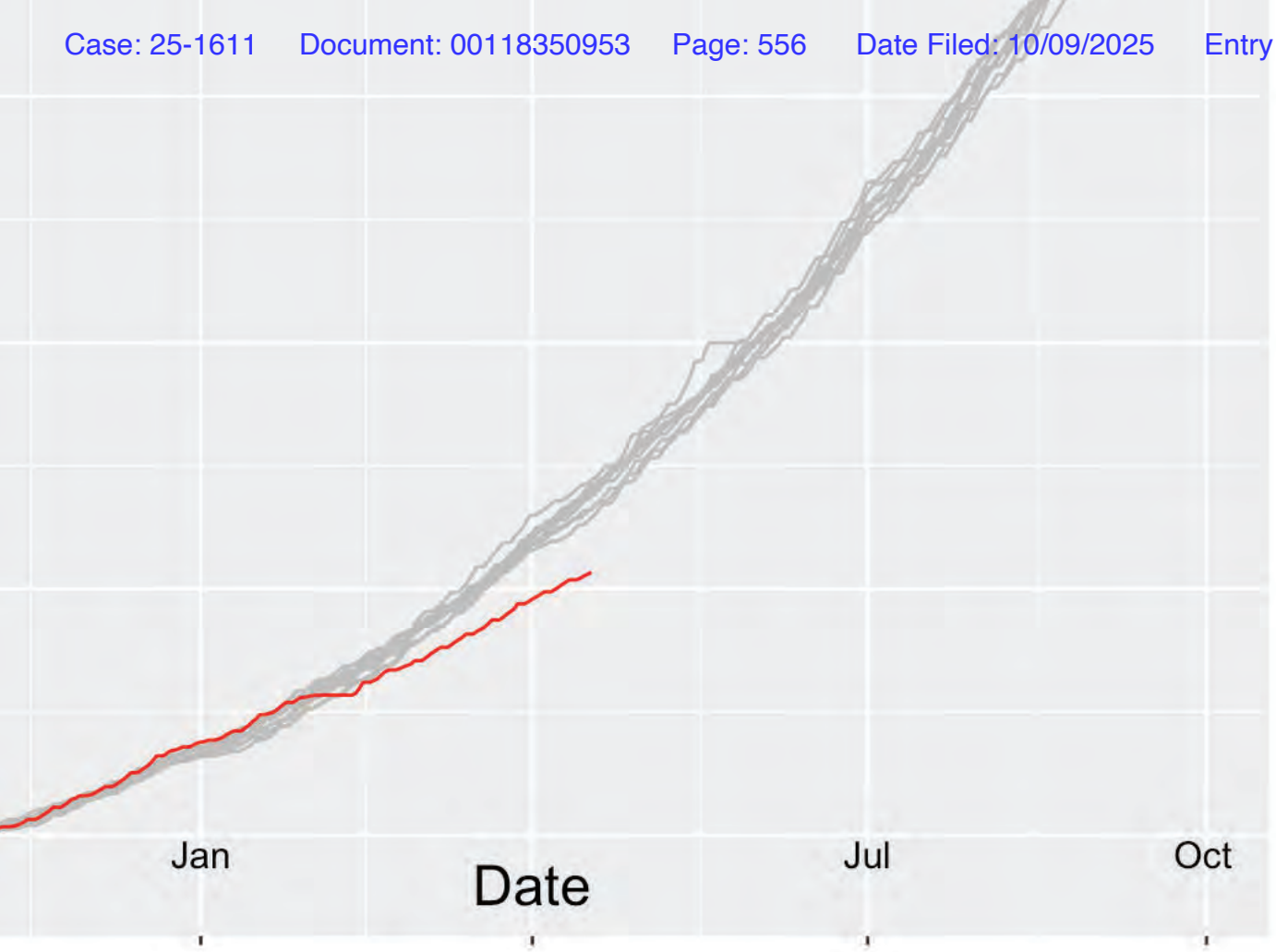
de in response to 83 Notices of Funding Opportunities (NOFOs). Of these NOFOs, 18 had a substa
of the biomedical workforce (hereafter “Diversity Opportunities”)

, 1075 had Project End Dates on or prior to 9/30/25. Thus, 21% of these NRSA awards will end by
s that were awarded in response to a Diversity Opportunity this percentage is slightly higher at 25%
s are 144 F31, 3 T32, and 15 T34.

extend past the end of this fiscal year, the number of grants anticipated to end is fiscal year 2026 i
nse to Diversity Opportunities. The activity codes for these applications are 205 F31, 1 F32, 11 T32

ntaining a robust NRSA portfolio

EXHIBIT B



ve for fiscal year 2025 started off along a normal curve but then, with the grant “pause” at the begi
ebruary 2025, the fiscal year 2025 diverged, lying below the other curves. It has remained there, du

ve sufficient time to release its full appropriation in fiscal

portant question but we need to make some assumptions.

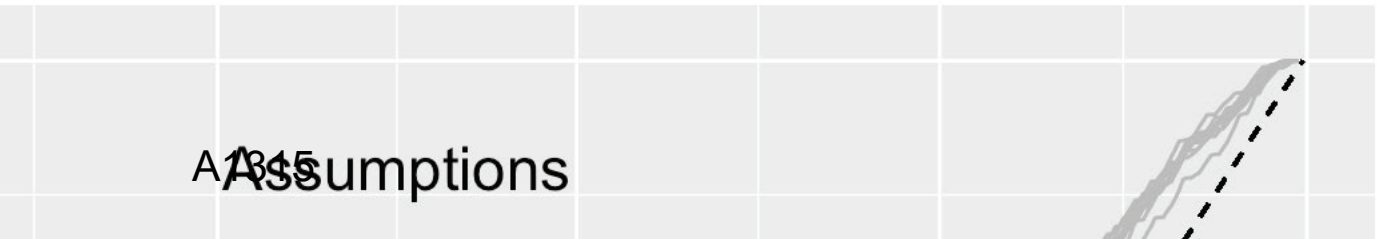
mptions are:

wards for fiscal year 2025 will be the same as that for fiscal year 2024.

ate will continue until some date;

ate will change to the 80th percentile rate from the previous years.

assumptions are shown below:



UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-WGY

SUPPLEMENTAL DECLARATION OF NICOLE MAPHIS

I, Nicole Maphis, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I provided a sworn declaration in this case dated April 20, 2025. I offer this additional declaration as a supplement to that first declaration.

2. On May 8, 2025, I checked the status of my pending MOSAIC K99/ROO application on the NIH era commons webpage. As shown on that webpage, my application status had changed to "Application withdrawn." A true and correct copy of that page is attached as Exhibit A.

3. That same page had a document entitled 'Administrative Withdrawal' linked to the Correspondence tab. I clicked on that link and found a notice from the Department of Health & Human Services, dated May 6, 2025, that reads: "This application responded to a discontinued program that no longer effectuated NIH priorities which included elements based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other

protected characteristics, which harms the health of Americans. Therefore, this application has been administratively withdrawn." A true and correct copy of this notice is attached as Exhibit B.

4. My pending MOSAIC K99/ROO application sought a grant to study the relationship between alcohol use and Alzheimer's Disease. That proposed study has no relationship to "DEI studies" as described in this May 6 notice.

5. I received no email or other notice from NIH informing me of this change in the status of my application or reason for that change.

I declare under penalty of perjury that the foregoing is true and correct.
Executed this 15th day of May, 2025.

Nicole M. Maphis

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-WGY

SUPPLEMENTAL DECLARATION OF KATIE EDWARDS

I, Katie Edwards, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I provided a sworn declaration in this case dated April 24, 2025. ECF No. 38-20. I offer this additional declaration as a supplement to that declaration.
2. I am offering this supplemental declaration in my individual capacity and not on behalf of my employer.
3. Since my April 24, 2025 declaration, I have had to reduce the hours of at least four team members whose jobs were funded largely or entirely through the terminated NIH grants that were discussed in that declaration. Specifically, those individuals were funded through the terminated R01 grant discussed in detail in that declaration (Project Number 5R01MD016384), and their work focused on the research funded through that grant. *See* ECF No. 38-20 ¶ 9. Prior to the termination of this grant, some of these individuals worked as many as ten to twenty hours a week on that project; now, because of this termination, they each work substantially fewer hours a week; they have consequently lost pay, and that reduction of hours has already had a substantial negative effect on this study.
4. As noted in my April 24, 2025 declaration, this grant funded a survey that collected data from over 3,100 participants. ECF No. 38-20 ¶ 11. Prior to the termination of the grant, the work of these individuals included sending out surveys every six months to participants,

following up with and sending reminders to the participants to complete their surveys, compensating participants as a result of their participation in the study, and generally liaising with and responding to study-related questions from the participants.

5. But because NIH terminated this grant, we have had to completely stop collecting data for this study, and we have put the study on hold, meaning most of the study's participants at this time are unable to complete all of the surveys the study originally set out to perform. *See* ECF No. 38-20 ¶¶ 11, 23. As I elaborated on in my April 24, 2025 declaration, cutting off the study prematurely will have several negative consequences for the study itself, the area of research, and the participants and communities served by this research. *See* ECF No. 38-20 ¶ 23.
6. Although my co-investigators and I have continued to try to raise funds to replace the funding from this grant and the other terminated NIH grants I mentioned in my April 24, 2025 declaration, I have to date only been able to raise approximately $10,000 in funds to replace those terminated funds. To put that figure in perspective, the award for just the R01 grant discussed above for just the 2025-2026 fiscal year amounted to over $750,000.00 in funding.
7. My co-investigators and I will keep trying to raise replacement funding. We are passionate about our field and work, and we are committed to addressing the health equity needs of our study participants and the broader populations served by our research. But I still do not anticipate being able to raise nearly enough money to secure the amount of funding (millions of dollars) that we would have had with the NIH grants that have been terminated since March 2025.
8. Without replacing the funding from those terminated grants, I anticipate having to let go of or substantially reduce the hours of far more staff members over the next few months. That would not only negatively affect their jobs and livelihoods, but it would also negatively affect the studies they work on, the participants they work with, and the populations who would be served by the research that will now be limited, stalled, or even fully cut off because of these terminations.
9. I have continued to regularly work more than 15 hours a day, trying to juggle my research with my efforts to replace funding lost because of these NIH grant terminations. But because I have had to focus so much on raising funds to make up for the loss of funding resulting

from the termination of the NIH grants, the amount of time I can spend conducting my research, reviewing literature, or designing new studies to address the public health needs of the communities served by my research has been significantly reduced.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 18 day of May, 2025.

Katie Edwards

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

SECOND SUPPLEMENTAL DECLARATION OF SCOTT W. DELANEY, ScD JD MPH

I, Scott W. Delaney, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am offering this Declaration in my individual capacity and not on behalf of my employer.

2. I previously set forth my professional background in two declarations. The first was my declaration filed on April 25, 2025, as Exhibit 27 attached to Plaintiffs' Motion for a Preliminary Injunction ("April 25 Declaration;" ECF No. 38-27). The second was my supplemental declaration filed on May 19, 2025, as Exhibit 45 attached to Plaintiff's Reply in Support of Plaintiffs' Motion for a Preliminary Injunction ("May 19 Declaration;" ECF No. 72-3).

3. Briefly, I am an epidemiologist and Research Scientist at the Harvard T.H. Chan School of Public Health (HSPH). I hold a Doctor of Science from HSPH (ScD, 2020) and have conducted epidemiologic research at HSPH in various capacities for 11 years. Throughout my career in epidemiology, I have applied for and received multiple types of grants from NIH either individually or as part of teams. Moreover, my current research activities are supported almost

entirely by NIH research grants. Based on these experiences, I am exceedingly familiar with a broad spectrum of grant mechanisms available from NIH.

4. I am also the co-founder of Grant Watch (https://grant-watch.us), a website and database that tracks terminated NIH grants. This effort began in early March 2025. Together with a colleague, Dr. Noam Ross of rOpenSci, we built the most comprehensive, up-to-date database of specific grants that NIH has terminated since February 28, 2025.

5. As explained in more detail in my April 25 Declaration, we aggregate data from multiple sources, including reports from Principal Investigators ("PIs") (i.e., scientists) whose grants were terminated; news reports; social media; Doge.gov; NIH's X feed; NIH RePORTER; USASpending.gov; the HHS TAGGS system; and a periodically published PDF list of terminated grants compiled and posted by HHS officials on the TAGGS website ("TAGGS PDF"). Based on our Grant Watch database, in my April 25 Declaration, I identified 755 grants that I believe were terminated for vague policy reasons. In my May 19 Declaration, I identified an additional 58 grants that I believe were terminated for similar reasons.

6. Since I compiled the list of terminated grants for my May 19 Declaration, we have learned of many more previously undisclosed grant terminations, primarily (though not exclusively) via updates to the TAGGS PDF and NIH RePORTER website. PIs with terminated grants have also submitted additional information to us. Accordingly, I have updated my count of terminated NIH grants using the same methods outlined in my April 25 Declaration.

7. As of Wednesday, June 4, 2025, at 11:00 p.m. Eastern Daylight Time, I have identified 924 more terminations beyond those previously identified in my earlier declarations. Thus, the combined total number of grants that NIH has terminated based on vague policy assertions is

1,737. A true and correct list of the 924 newly identified grant terminations is attached to this Second Supplemental Declaration as Exhibit A.

8. Using methods previously described in Paragraphs 14-15 of my April 25 Declaration, I quantified the financial value of these newly undisclosed terminations. The total budget originally allocated to the 924 grants was approximately $1.9 billion. As before, most grants were terminated midstream after Principal Investigators had already spent a portion of the budgets. As a result, $1.0 billion had already been spent on these projects, leaving the aggregate unspent value of these grants at approximately $874 million.

9. I also calculated the financial value of all 1,737 terminated NIHs grant. The aggregate total budget for these grants was approximately $7.2 billion. Prior to termination, PIs has spent approximately $3.8 billion of these grants, leaving $3.4 billion in unspent grant funds.

10. Among the 924 newly disclosed terminated grants was Grant R36AG087312 entitled "An analysis of the multi-level factors that impact provision of emergency medical services to Hispanic older adults." This was a dissertation award. As such, it provided a small stipend and tuition remittance to a graduate student while she completed her PhD program studying why older Hispanic adults in the United States receive fewer emergency medical services.

11. Another example of a newly disclosed terminated grant was entitled "Predicting psychosocial adjustment in pediatric cochlear implant users" (Grant number R01DC021339). This was a study to understand the effects of stress on babies and toddlers who lose their hearing, and on how cochlear implants to restore their hearing—along with other stress-reducing coping strategies—may promote healthy child brain development. The topic of this research grant did not fall within the proscribed categories as best as I am able to understand them. For example,

this was not a "DEI" grant in any way, nor was it a grant focused on the health of the transgender community, or a study on any other disfavored topic.

12. Notably, however, the Principal Investigator of Grant R01DC021339 was from a demographic background that is underrepresented in scientific research, and the PI applied for the grant under an NIH grant mechanism that was meant to support such researchers. Specifically, the grant was issued under the Funding Opportunity Announcement entitled "NIDCD Research Opportunities for New Investigators to Promote Workforce Diversity" (RFA-DC-23-001).

13. Grant K99AG086530, entitled "Alzheimer's Disease and Related Dementia neuropathologies and exposures to traffic pollution mixtures" was also among the newly disclosed terminations. This was an early career development award to a researcher studying whether and how air pollution from vehicles with combustion engines (i.e., most cars and trucks) affects brain tissue pathology that may cause Alzheimer's Disease. Like the PI of the grant discussed directly above in Paragraphs 11-12, the PI of Grant K99AG086530 applied under a grant mechanism that sought to diversify our scientific workforce.

14. Separately, Grant R00ES031050-04S1, entitled "A systematic study of the environmental etiology of autism spectrum disorder using high-throughput behavioral screening" was recently terminated. The topic of this grant—aptly explained by its title—seems wholly consistent with public statements from Trump Administration officials about their policy priorities. Specifically, I am aware of press reports detailing statements from the HHS Secretary and others emphasizing that the Trump Administration is prioritizing research that explores the causes of autism spectrum disorder. Notwithstanding this grant's concordance with the Trump Administration's priorities, it was terminated, likely because it was issued under a grant mechanism that, again,

was meant to support researchers from underrepresented backgrounds. Specifically, this grant was issued under PA-23-189, which was entitled "Research Supplements to Promote Diversity in Health Related Research."

15. These newly disclosed grants join others previously reported in my April 25 Declaration or my May 19 Declaration. One example of a terminated grant from those earlier declarations is Grant R01MH134051, which supported research at the University of Central Florida into ways to prevent suicide among Black sexual and gender minority teenagers. Another example included in prior declarations is Grant R01ES035053, which was a five-year grant to study reasons why Black women in the United States have higher rates of infertility than White women.

16. In general, terminated grants listed in exhibits to this declaration and to both of my prior declarations are consistent insofar as they cover a wide spectrum of critical health science research conducted by a diverse group of scientists at universities all across the United States. Based on my experience investigating terminated grants, there I believe these terminations will continue for the foreseeable future.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 5 day of June, 2025.

SCOTT W. DELANEY

Exhibit A

Award Number	Project Title	Awardee Organization	Termination Date*
R35GM142863	Advancing Methods in Infectious Diseases Models: Incorporating Structural Causes	BOSTON COLLEGE	*
K99AG083239	The Role of Nuclear Factor Erythroid 2-related factor 2 in Sarcopenic Obesity	LSU PENNINGTON BIOMEDICAL RESEARCH CTR	*
R01ES031585-04S1	Particulate exposure and kidney health	UNIVERSITY OF COLORADO DENVER	*
R01MD019684	Examining the determinants and consequences of supportive care medication use disparities in patients with pancreatic cancer: A sequential mixed-methods approach	UNIVERSITY OF FLORIDA	*
F31AG080941	Characterizing Alzheimers Disease and Serious Mental Illness Co-Occurrence Among Nursing Home Residents and Relationship to Symptomatology and Care Practices	UNIVERSITY OF WISCONSIN-MADISON	*
F31AI176821	Uncovering the role of cardiolipin in promoting gasdermin D-mediated necroptosis and hyperinflammation	VANDERBILT UNIVERSITY	*
R01DC020279-03S1	Social learning enhances auditory cortex sensitivity and task acquisition	NEW YORK UNIVERSITY	*
R01DC021339	Predicting psychosocial adjustment in pediatric cochlear implant users	INDIANA UNIVERSITY INDIANAPOLIS	*
R01DE031812-03S1	Angiogenic and anti-microbial supports for pulp regeneration	NEW JERSEY INSTITUTE OF TECHNOLOGY	*
R01EY033772-02S1	Molecular specification of dopaminergic neuron diversity	BAYLOR COLLEGE OF MEDICINE	*
R01HD104801-04S1	Prenatal Social Connection and Disruption During the COVID-19 Pandemic: Effects on Maternal and Infant Health	UNIVERSITY OF SOUTHERN CALIFORNIA	*
R21DK135039	Developmental effects of intestinal microbes on metabolic and behavioral circadian rhythms	UNIVERSITY OF WISCONSIN-MADISON	*
R25AG076399	Engaging Underrepresented Racial/Ethnic Minority Students in Aging Research	CHARLES R. DREW UNIVERSITY OF MED & SCI	*
R25AG076410	Investigators from Novices, a Transdisciplinary Research Education Program to Increase Diversity (INTREPID) in Aging Research	UNIVERSITY OF CENTRAL FLORIDA	*
R25GM146287	Linking Science, Mathematics and Literacy for All Learners	UNIVERSITY OF MISSOURI-COLUMBIA	*
R25GM150166	Community-engaged research partnerships for building capacity and training in inclusive data science	OREGON HEALTH & SCIENCE UNIVERSITY	*
F31AG085938	Evaluating social and clinical risk factors for the progression from Mild Cognitive Impairment to Alzheimer's Disease and Related Dementias using Real World Clinical Data	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	*
F31AI183803	An iPSC-derived human organoid based model of intestinal filovirus infection	BOSTON UNIVERSITY MEDICAL CAMPUS	*
F31DC021084	Anatomy and Function of a Fungiform Specific Mechanoreceptor	UNIVERSITY OF LOUISVILLE	*
R01AI177624-01A1S1	A novel CRISPR/Cas12 system targeting HBV DNA for gene therapy	EAST TENNESSEE STATE UNIVERSITY	*
R01DA060066	Combination of THC and CBD as a Novel Treatment for Co-Occurring Opioid Addiction and Chronic Pain	YALE UNIVERSITY	*
R01DC007176-19S1	Regulation of taste neuron morphology and function	UNIVERSITY OF LOUISVILLE	*
R01DC021337	Disruption of lateralized auditory cortical function in a mouse model of Rett Syndrome	WASHINGTON UNIVERSITY	*
R01HD101406-04S1	Development and Persistence of Tissue-Level Musculoskeletal Deformity Following Brachial Plexus Birth Injury	NORTH CAROLINA STATE UNIVERSITY RALEIGH	*
R25AG043364	SDSU ADAR Program	SAN DIEGO STATE UNIVERSITY	*
R25AI175048	Infectious Diseases Summer Program Integrating Research at Emory (INSPIRE)	EMORY UNIVERSITY	*
R25AI179580	Rice-HCC ACCELERATE: Augmenting Community College Education to Leverage Experiential Research and Advance Training Equity	RICE UNIVERSITY	*
R25DC020697	Development of a diverse workforce through mentoring networks among otitis media researchers	UNIVERSITY OF COLORADO DENVER	*
R25DK113652	UAB STEP-UP: Promoting Diversity through Team Mentored Research Experiences	UNIVERSITY OF ALABAMA AT BIRMINGHAM	*
R25DK118761	AGA FORWARD PROGRAM - Fostering Opportunities Resulting in Workforce and Research Diversity	AMERICAN GASTROENTEROLOGICAL ASSN/INST	*
R25DK118761-07S1	AGA FORWARD PROGRAM - Fostering Opportunities Resulting in Workforce and Research Diversity	AMERICAN GASTROENTEROLOGICAL ASSN/INST	*
R25DK135989	Enhancing Workforce Diversity in the Bone, Mineral, and Musculoskeletal Field	AMERICAN SOCIETY FOR BONE & MINERAL RES	*
R25ES025505	Undergraduate Research Program to Promote Diversity in EHS	COLUMBIA UNIVERSITY HEALTH SCIENCES	*
R25GM142031	Learning and Discovery in Experimental Environmental Health Science: On the Path from Data to Knowledge	UNIVERSITY OF WISCONSIN MILWAUKEE	*
R25GM154344	Addictive Behaviors: A collaborative co-design program to promote health literacy and career awareness in high schools	TUFTS UNIVERSITY BOSTON	*

* Denotes grants where the precise termination date is not yet known, but which was after February 28, 2025. As of June 4, 2025, termination dates for these grants listed in various federal databases, including NIH RePORTER and HHS TAGGS, conflict. As the federal databases update over time, we expect these conflicts to resolve. Notwithstanding the uncertainty, archived data from federal databases demonstrates the terminations occurred after February 28, 2025.

R01DC020965-02S1	Research Supplement: Naturalistic Neuroimaging for Presurgical Language Mapping	BRIGHAM AND WOMEN'S HOSPITAL	2025-03-01
F31MH136812	Impact of social environment on cognitive development and thalamocortical maturation	COLUMBIA UNIVERSITY HEALTH SCIENCES	2025-03-08
K24DA042720	Midcareer K24 Award for Mentoring and Patient-Oriented Research	SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH	2025-03-08
R01NR021108	Integrated Supportive Care Policies to Improve Maternal Health Equity: Evaluating the Multi-level Effects and Implementation of Doula Programs for Medicaid-Eligible Birthing People in New York City	COLUMBIA UNIVERSITY HEALTH SCIENCES	2025-03-08
R25NS076445	Summer Program for Undergraduate Rising Stars (SPURS), a Columbia University biomedical sciences pipeline program	COLUMBIA UNIVERSITY HEALTH SCIENCES	2025-03-08
R25NS115551	Brain Research Apprenticeships in New York at Columbia (BRAINYAC)	COLUMBIA UNIV NEW YORK MORNINGSIDE	2025-03-08
R41MD019548	A Biobased Biodegradable Sunscreen that is Safe, Removes Environmental Impact, is Inclusive of all Skin Tones, and is for the Purpose of Eliminating Disparities in Melanoma Mortality Rates	OLIPHA INC	2025-03-12
F32AG084196	Reversal of Tau Pathology to Rescue Serotonergic Function in Early Alzheimer's Disease	UNIVERSITY OF IOWA	2025-03-17
P50MD017348-04S1	The Mid-Atlantic Center for Cardiometabolic Health Equity (MACCHE)	JOHNS HOPKINS UNIVERSITY	2025-03-28
P50MD017366-04S1	UCLA-UCI Center for Eliminating Cardiometabolic Disparities in Multi-Ethnic Populations (UC END DISPARITIES)	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-03-28
R01MD013969-05S1	Reducing Disparity in Receipt of Mother's Own Milk in Very Low Birth Weight Infants: An Economic Intervention to Improve Adherence to Sustained Maternal Breast Pump Use	RUSH UNIVERSITY MEDICAL CENTER	2025-03-28
R01MD014020-05S1	Collateral Consequences of Parents Incarcerations for Their Adolescent Children: A Prospective Longitudinal Study	NORTHWESTERN UNIVERSITY AT CHICAGO	2025-03-28
R01MD014127-05S1	Achieving American Indian Youth Energy and Mental Health Balance	UNIVERSITY OF ARIZONA	2025-03-28
R01MD014145-05S1	A Coping Skills Intervention for Low-SES Latino Families of Children with Asthma	UNIVERSITY OF TEXAS AT AUSTIN	2025-03-28
R01MD014694-05S1	Post Maria Puerto Rican Families Relocated to Florida: A Multisite Study of Alcohol Misuse and Mental Health Problems	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	2025-03-28
R01MD015165-04S1	Multilevel Physical Activity Intervention For Low Income Public Housing Residents - Diversity Supplement	TUFTS MEDICAL CENTER	2025-03-28
R01MD015715-04S1	Social-Environmental Predictors of Sleep Disparities During the Transition to College	FORDHAM UNIVERSITY	2025-03-28
R01MD015729-04S1	Targeting Health Disparities through Housing Redevelopment: A Natural Experiment of Housing Quality, Stability, and Economic Integration	BOSTON COLLEGE	2025-03-28
R01MD015904-05S1	Social Isolation and Discrimination as Stressors Influencing Brain-Gut Microbiome Alterations among Filipino and Mexican American	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-03-28
R01MD016046-03S1	Structural Racism and Adverse Birth Outcomes in the US South: A Multigenerational Perspective	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-03-28
R01MD016071-04S1	Understanding health disparities in Pakistani, Bangladeshi and Asian Indian immigrants: the role of socio-cultural context, acculturation and resilience resources - Supplement	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-03-28
R01MD016401-04S1	JAK-STAT Inhibition to Reduce Racial Disparities in Kidney Disease	DUKE UNIVERSITY	2025-03-28
R01MD016465-04S1	Video-based Intervention to Reduce Treatment and Outcome Disparities in Adults Living with Stroke or Transient Ischemic Attack (VIRTUAL)	UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON	2025-03-28
R01MD016595-03S1	Common and Distinct Influences of Prenatal and Postnatal Early-Life Adversity on Epigenomic Trajectories in Mexican American Children	UNIVERSITY OF CALIFORNIA BERKELEY	2025-03-28
R01MD017006-03S1	Migrant and Multi-generational Immigrant Experiences: The Effects of Stressors on Epigenetic, Behavioral, and Health-related Outcomes - Diversity Supplement	WAKE FOREST UNIVERSITY HEALTH SCIENCES	2025-03-28
R01MD017048-04S1	Hidden in Plain Sight: Stigmatizing Language in Patient Medical Records	JOHNS HOPKINS UNIVERSITY	2025-03-28
R01MD017526-03S1	Assessing TRUE HAVEN Housing Intervention Impact on Parent Experiences and Youth Mental Health	YALE UNIVERSITY	2025-03-28
R01MD017619-03S1	Impacts of Parental Workplace Social Status on Disparities in Infant and Child Health	OHIO STATE UNIVERSITY	2025-03-28
R01MD017961-03S1	Preparing a Food Insecurity Intervention for Implementation	INDIANA UNIVERSITY INDIANAPOLIS	2025-03-28
R01MD018204-03S2	Building Access to Food through Systems and Solidarity	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	2025-03-28
R01MD018265-03S2	Longitudinal Study of Early NAFLD Progression and the Gut Microbiome in Asian Americans, Native Hawaiians and Whites	UNIVERSITY OF HAWAII AT MANOA	2025-03-28
R01MD019027-02S1	Factors Influencing Pediatric Asthma into Adulthood (FIPA2)	MISSOURI BREAKS RESEARCH, INC.	2025-03-28
R42MD014075-04S1	Good Bowls: Empowering Communities to Achieve Good Food Access and Health Equity	EQUITI FOODS, LLC	2025-03-28
F31AI176806	Host-pathogen interactions and carbon processing in glycerol kinase deficient Mycobacterium tuberculosis	RUTGERS BIOMEDICAL AND HEALTH SCIENCES	2025-03-31
F31AI176816	Investigating a Role for Antigen Presentation by Enteric Glial Cells in Experimental Autoimmune Encephalomyelitis	UNIVERSITY OF VIRGINIA	2025-03-31

F31AI181454	Novel Family of Dual Membrane-Spanning Anti-sigma factors Regulate OMV Biogenesis in Bacteroides thetaiotaomicron	WASHINGTON UNIVERSITY	2025-03-31
F31AI183831	Discovering how Mycobacterium tuberculosis promotes its survival in neutrophils	WASHINGTON UNIVERSITY	2025-03-31
F31DA059982	Epigenetic Mechanisms Underlying Drug-seeking Behavior: Role of HDAC3 in Regulating Gene Expression within the MHb Cholinergic Population for Cocaine-induced Relapse-like Behavior	UNIVERSITY OF CALIFORNIA-IRVINE	2025-03-31
F31DA060046	Dopamine Projections to the Amygdala in Goal-Directed and Habit Learning	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-03-31
F31MH136804	The dCA1-LS-VTA Pathway in 14-3-3 Deficiency Induced Hyperlocomotor Behavior and Overactive Dopamine Signaling	FLORIDA STATE UNIVERSITY	2025-03-31
F32AG082458	Comparison of direct and indirect magnetic resonance imaging of myelin in Alzheimer's disease	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-03-31
K00AG084261	Deciphering the Role of Noradrenergic Receptors during Neuromodulation in Alzheimer's Disease	COLUMBIA UNIV NEW YORK MORNINGSIDE	2025-03-31
K00DA059288	Measuring effects of morphine withdrawal on dopaminergic salience coding across the striatum	VANDERBILT UNIVERSITY	2025-03-31
K99GM154061	Investigating UPF3 paralog function in Nonsense-Mediated mRNA Decay and Genetic Compensation	OHIO STATE UNIVERSITY	2025-03-31
K99GM154062	Elucidating the sterol-sensing mechanisms that regulate lipid metabolism.	UT SOUTHWESTERN MEDICAL CENTER	2025-03-31
P50MD017342-04S3	Understanding facilitators and barriers for the utilization of an Indigenized meal kit amongst urban Minnesota Native American youth and families	UNIVERSITY OF MINNESOTA	2025-03-31
R01AG071815-03S1	Novel longevity enhancing pathways regulated by mTOR	DREXEL UNIVERSITY	2025-03-31
R01CA206458-09S1	Exosome secretion in breast cancer progression	VANDERBILT UNIVERSITY	2025-03-31
R01CA248930-05S1	TRIM37 is a genetic determinant of racial disparity in metastatic TNBC patients	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-03-31
R01CA251547-04S1	The Role of Implicit Bias on Outcomes of Patients with Advanced Solid Cancers	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2025-03-31
R01CA254628-04S1	Effectiveness and implementation of a health system intervention to improve quality of cancer care for rural, underserved patients	UNIVERSITY OF IOWA	2025-03-31
R01CA262055-03S1	Metabolic regulation and inhibition of ATP-citrate lyase	UNIVERSITY OF PENNSYLVANIA	2025-03-31
R01CA262123-02S1	Personalized vaccine immunotherapy in combination with anti-PD 1 antibody for recurrent or metastatic squamous cell carcinoma of the head and neck	EMORY UNIVERSITY	2025-03-31
R01CA279585-02S1	The genetics of tumor suppression by p53 - Diversity Supplement	WISTAR INSTITUTE	2025-03-31
R01DC019769-03S1	Investigation of Inflammatory Responses in the Olfactory System	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-03-31
R01DC020447-02S1	Talking Late in Two Languages	UNIVERSITY OF WISCONSIN-MADISON	2025-03-31
R01DC021075	Investigating the mechanisms of stereocilia length regulation and innovative strategies for restoring hearing	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-03-31
R01EY034097-03S1	Regulation of successful optic nerve regeneration by the mevalonate/cholesterol pathway	MEDICAL COLLEGE OF WISCONSIN	2025-03-31
R01GM149646-02S1	Administrative Supplement - Designing peptide macrocycles to selectively inhibit BET proteins: Martinez Noa, Yisel	UNIVERSITY OF FLORIDA	2025-03-31
R01LM013897-03S1	An informatics framework for single-cell multi-omics from clinical specimens	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-03-31
R25AG046114	Multidisciplinary undergraduate training program in Health-assistive Smart Environments	WASHINGTON STATE UNIVERSITY	2025-03-31
R25AG050484	South Carolina - Advancing Diversity in Aging Research Undergraduate Program	UNIVERSITY OF SOUTH CAROLINA AT COLUMBIA	2025-03-31
R25AG060892	Katies for Aging Research and Equity (KARE)	ST. CATHERINE UNIVERSITY	2025-03-31
R25AG060912	Enhancing UNderGraduate Education and Research in AGing to Eliminate Health Disparities	WAKE FOREST UNIVERSITY HEALTH SCIENCES	2025-03-31
R25AG081171	Inspiring Undergraduate Student Training in Alzheimer's Research	THOMAS JEFFERSON UNIVERSITY	2025-03-31
R25AG086117	Duke/UNC ADAR Program	DUKE UNIVERSITY	2025-03-31
R25AG086122	Pipeline in Aging Research Career Training (PACT)	GEORGETOWN UNIVERSITY	2025-03-31
R25AG086126	Diversity in Research Education in Aging Medicine and Science	UNIVERSITY OF ARIZONA	2025-03-31
R25AI181750	HBCU/MSI Mentored Research Program in the Structural Biology of Human Pathogens	MEHARRY MEDICAL COLLEGE	2025-03-31
R25DC020919	IMPACT: Promoting Diversity and the Success of Underrepresented Minority Students in the Clinical and Research Workforce for Communication Sciences and Disorders	CASE WESTERN RESERVE UNIVERSITY	2025-03-31
R25DC020920	Fostering Underrepresented Employees' Resilience and Zeal for Academia (FUERZA)	UNIVERSITY OF ARIZONA	2025-03-31
R25DC021651	Monell Science Apprenticeship Program: Inspiring Biomedical Careers In Underrepresented Undergraduates	MONELL CHEMICAL SENSES CENTER	2025-03-31
R25DK078381	Promoting diversity in research careers in diabetes, digestive and kidney diseases	UNIVERSITY OF TEXAS HLTH SCIENCE CENTER	2025-03-31
R25DK078386	Pacific High Schools STEP-UP to One Health	UNIVERSITY OF HAWAII AT MANOA	2025-03-31
R25DK096937	Future Leaders Advancing Research in Endocrinology (FLARE): Professional Development for Underrepresented Trainees and Junior Faculty	ENDOCRINE SOCIETY	2025-03-31

R25DK096944	APA Research in Academic Pediatrics Initiative on Diversity (RAPID)	ACADEMIC PEDIATRIC ASSOCIATION	2025-03-31
R25DK118763	Research Leadership Development Program for Diverse Early Career Scientists	AMERICAN PSYCHOLOGICAL ASSOCIATION	2025-03-31
R25DK132963	Wake Forest School of Medicine Short-Term Research Experience Program to Unlock Potential	WAKE FOREST UNIVERSITY HEALTH SCIENCES	2025-03-31
R25DK132965	Genomics STEP-UP High School Coordinating Center Region A; Increasing Diversity Through Genomics Research Experiences	COLD SPRING HARBOR LABORATORY	2025-03-31
R25DK132966	Summer Program for the Advancement of Research Relevant to NIDDK (SPARK)	WASHINGTON UNIVERSITY	2025-03-31
R25DK139637	U of U Step Up	UNIVERSITY OF UTAH	2025-03-31
R25GM146300	The Brain Explorer Academy (BEA): An Informal Science Education Partnership	UNIVERSITY OF CALIFORNIA-IRVINE	2025-03-31
R35GM128822-06S1	Transposon-mediated rewiring of gene regulatory networks	UNIVERSITY OF COLORADO	2025-03-31
R35GM148219-02S1	Deep Learning Models for Metabolomics Analysis	TUFTS UNIVERSITY MEDFORD	2025-03-31
R35GM153204-01S1	UG Diversity Supplement: Epithelial cell-cell junction remodeling in response to cell- and tissue-scale forces	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-03-31
R37AI148064-13S1	HIV immune evasion and escape through T cell virological synapses	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2025-03-31
R37CA248631-04S1	Davoli/Camacho-Hernandez Diversity Supplement	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	2025-03-31
U01CA195568-09S1	The Lymphoma Epidemiology of Outcomes (LEO) Cohort Study (Diversity Supplement - Alexis Romero)	MAYO CLINIC ROCHESTER	2025-03-31
U01CA195568-09S2	The Lymphoma Epidemiology of Outcomes (LEO) Cohort Study (Diversity Supplement - Mazie Tsang)	MAYO CLINIC ROCHESTER	2025-03-31
U01MD019540-02S1	Train and EMPOWER A Community Health workforce to achieve equity and reduce disparities in mental health (TEACH)	UNIVERSITY OF TEXAS ARLINGTON	2025-03-31
DP2AI154420-04S1	Connecting the Spatiotemporal Organization of Gut Bacterial Communities to the Emergence and Spread of Antibiotic Resistance	UNIVERSITY OF CALIFORNIA-IRVINE	2025-04-02
DP2AI154450-04S1	Harnessing Stem-like CD8 T Cells for Immunotherapies to Eradicate HIV Reservoirs	UT SOUTHWESTERN MEDICAL CENTER	2025-04-02
F31AI189116	Studies on the SARS-CoV-2 Main Protease Dimerization Mechanism	UNIVERSITY OF TEXAS HLTH SCIENCE CENTER	2025-04-02
F31GM151758	The Development of Novel Anion Receptors for Reactive Sulfur, Oxygen, and Nitrogen Species	UNIVERSITY OF OREGON	2025-04-02
F31GM156104	Elucidating the Neuropeptidome Implicated in Crustacean Feeding Processes through Multiplexed Data-Independent Acquisition Mass Spectrometry	UNIVERSITY OF WISCONSIN-MADISON	2025-04-02
K12GM068524	San Diego IRACDA Scholars Program	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-02
T32GM148394	G-RISE at New Mexico State University	NEW MEXICO STATE UNIVERSITY LAS CRUCES	2025-04-02
DP1DA054344-03S1	X chromosome inactivation in sex disparities to substance use disorder	OHIO STATE UNIVERSITY	2025-04-03
R01DA045016-08S1	Evaluating the Effect of E-cigarette Policies on Youth Tobacco Use	UNIVERSITY OF MISSOURI-COLUMBIA	2025-04-03
R01DA050670-04S2	CHOICES-TEEN: Efficacy of a Bundled Risk Reduction Intervention for Juvenile Justice Females	BAYLOR UNIVERSITY	2025-04-03
R01DA051127-04S1	Neurobiological susceptibility to peer influence and drug use in adolescence	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-03
R01DA054094-04S1	Probing the role of a hypothalamic-thalamic-striatal circuit in cue-driven behaviors	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-04-03
R01DA054220-04S1	SOAR: Smartphones for Opioid Addiction Recovery	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	2025-04-03
R01DA055673-03S1	Exploring the accessibility, acceptability, and utilization of a community-based harm reduction vending machine among persons with limited opportunity structures.	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-03
R01DA055839-02S1	The influence of social stress on polysubstance use and addiction vulnerability among adults in communities of color: The mediating role of psychological pain	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-04-03
R01DA056499-03S1	Leveraging quasi-experimental methods to examine the longitudinal relations among legal system exposure, substance use, neurocognition, and education	UNIVERSITY OF MINNESOTA	2025-04-03
R01DA056592-02S1	Targeting gut brain-signaling to reduce cocaine seeking behaviors	WAKE FOREST UNIVERSITY HEALTH SCIENCES	2025-04-03
R01DA056602-03S1	Multiomic profiling of cell types mediating opioid use disorder in rats	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-03
R01DA057195-02S1	Cellular and circuitry mechanisms of NRTI-induced pain pathogenesis in the context of opioids and HIV	STATE UNIVERSITY NEW YORK STONY BROOK	2025-04-03
R01DA057789-02S1	Substance use disorder treatment centers and facility ownership changes	YALE UNIVERSITY	2025-04-03
T34GM136450	U-RISE Training the Next Generation of Basic Biomedical Researchers A Holistic Approach	CALIFORNIA STATE UNIVERSITY NORTHRIDGE	2025-04-03
T34GM136467	U-RISE at California State University San Bernardino	CALIFORNIA STATE UNIV SAN BERNARDINO	2025-04-03
T34GM136477	U-RISE at Delaware State University: Student Training in Academic Research	DELAWARE STATE UNIVERSITY	2025-04-03
T34GM136492	U-Rise at Rowan University	ROWAN UNIVERSITY	2025-04-03

T34GM136495	U-RISE at Claflin University through Collaborative Interdisciplinary Mentoring in Biomedical Sciences	CLAFLIN UNIVERSITY	2025-04-03
T34GM140909	U-RISE at Fort Lewis College	FORT LEWIS COLLEGE	2025-04-03
T34GM140930	U-RISE at California State University Dominguez Hills	CALIFORNIA STATE UNIV-DOMINGUEZ HILLS	2025-04-03
T34GM141009	U-RISE at the University of Alaska Fairbanks	UNIVERSITY OF ALASKA FAIRBANKS	2025-04-03
T34GM141989	U-RISE at Portland State University	PORTLAND STATE UNIVERSITY	2025-04-03
T34GM141990	U-RISE AT DILLARD UNIVERSITY	DILLARD UNIVERSITY	2025-04-03
T34GM145334	U-RISE at Tennessee State University	TENNESSEE STATE UNIVERSITY	2025-04-03
T34GM145384	U-Rise at California State University Bakersfield	CALIFORNIA STATE UNIVERSITY BAKERSFIELD	2025-04-03
T34GM145385	U-RISE at University of North Florida	UNIVERSITY OF NORTH FLORIDA	2025-04-03
T34GM145400	U-RISE at San Francisco State University	SAN FRANCISCO STATE UNIVERSITY	2025-04-03
T34GM145404	U-RISE at University of Puerto Rico at Cayey	UNIVERSITY OF PR CAYEY UNIVERSITY COLL	2025-04-03
T34GM145428	U-Rise at the University of New Mexico	UNIVERSITY OF NEW MEXICO	2025-04-03
T34GM145466	U-RISE at the University of North Dakota	UNIVERSITY OF NORTH DAKOTA	2025-04-03
T34GM145503	Undergraduate Research Training for Student Enhancement (U-RISE) at Cal State LA	CALIFORNIA STATE UNIVERSITY LOS ANGELES	2025-04-03
T34GM145504	U-RISE AT UNIVERSITY OF PUERTO RICO AT PONCE	UNIVERSITY OF PUERTO RICO PONCE	2025-04-03
T34GM145505	U-RISE at PVAMU	PRAIRIE VIEW AGRI & MECH UNIVERSITY	2025-04-03
T34GM145511	U-RISE at UC Merced	UNIVERSITY OF CALIFORNIA, MERCED	2025-04-03
T34GM145513	U-RISE at Howard University	HOWARD UNIVERSITY	2025-04-03
T34GM145521	U-RISE at the New Jersey Institute of Technology	NEW JERSEY INSTITUTE OF TECHNOLOGY	2025-04-03
T34GM145525	U-RISE at the University of Puerto Rico at Humacao	UNIVERSITY OF PUERTO RICO AT HUMACAO	2025-04-03
T34GM145542	Rochester Institute of Technology U-RISE Scientists-in-Training Program for Deaf and Hard-of-Hearing Undergraduates (RIT U-RISE)	ROCHESTER INSTITUTE OF TECHNOLOGY	2025-04-03
T34GM149378	Undergraduate Research Training Initiative for Student Enhancement (U-RISE) (T34) at CSULB	CALIFORNIA STATE UNIVERSITY LONG BEACH	2025-04-03
T34GM149385	U-RISE at Lehman College	HERBERT H. LEHMAN COLLEGE	2025-04-03
T34GM149392	U-RISE at the University of the Virgin Islands	UNIVERSITY OF THE VIRGIN ISLANDS	2025-04-03
T34GM149448	Kean University U-RISE Trainee Pathway (KUTP)	KEAN UNIVERSITY	2025-04-03
T34GM149493	U-RISE at Cal State Fullerton	CALIFORNIA STATE UNIVERSITY FULLERTON	2025-04-03
T34GM149494	UNC-Greensboro U-RISE: Engage, Sustain, and Prepare Future PhD Biomedical Scientists	UNIVERSITY OF NORTH CAROLINA GREENSBORO	2025-04-03
T34GM149816	U-RISE at Old Dominion University	OLD DOMINION UNIVERSITY	2025-04-03
T34GM153398	U-RISE at Sacramento State	CALIFORNIA STATE UNIVERSITY SACRAMENTO	2025-04-03
T34GM153552	U-RISE at Worcester Polytechnic Institute (U-RISE@Wπ)	WORCESTER POLYTECHNIC INSTITUTE	2025-04-03
T34GM153558	Medgar Evers College Undergraduate Research Training Initiative for Student Enhancement (U-RISE)	MEDGAR EVERS COLLEGE	2025-04-03
T34GM153561	The University of Hartford U-RISE Program	UNIVERSITY OF HARTFORD	2025-04-03
T34GM153567	U-RISE at NMSU	NEW MEXICO STATE UNIVERSITY LAS CRUCES	2025-04-03
T34GM153625	U-RISE at Sam Houston State University	SAM HOUSTON STATE UNIVERSITY	2025-04-03
T34GM153651	NCA&TSU Undergraduate Research Training Initiative for Student Enhancement (U-RISE)	NORTH CAROLINA AGRI & TECH ST UNIV	2025-04-03
T34GM153667	URISE at the University of Puerto Rico Rio Piedras	UNIVERSITY OF PUERTO RICO RIO PIEDRAS	2025-04-03
U01DA041089-10S1	5/21 ABCD-USA Consortium: Research Project Site at UC San Diego	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-03
U01DA043799-09S1	Identification of Genetic Variants that Contribute to Compulsive Cocaine Intakein Rats	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-03
U01DA051234-04S1	Characterization of Tandem Repeat and Structural Variants Contributing to Addictive Behaviors in Mice and Rats	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-03
U01DA054170-04S2	Spatial analyses of marmoset germline development	UNIVERSITY OF TEXAS SAN ANTONIO	2025-04-03
U01DA055316-04S2	16/24 Healthy Brain and Child Development National Consortium HEAL Diversity Supplement	UNIV OF MARYLAND, COLLEGE PARK	2025-04-03
U01DA055355-04S1	9/24- Healthy Brain and Child Development National Consortium	NORTHWESTERN UNIVERSITY AT CHICAGO	2025-04-03
U01DA055357-03S1	An examination of recruitment and retention for clinical infant neuroimaging studies	VIRGINIA POLYTECHNIC INST AND ST UNIV	2025-04-03
U01DA055363-04S1	The Transgenerational Influence of Discrimination on Mental Health	OREGON HEALTH & SCIENCE UNIVERSITY	2025-04-03
U01DA055369-04S1	14/24 The Healthy Brain & Child Development National Consortium	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-03

U54DA058271-02S1	Penn State TCORS: Tobacco Product Composition Effects on Toxicity and Addiction	PENNSYLVANIA STATE UNIV HERSHEY MED CTR	2025-04-03
R01DA057886-02S1	Social determinants of health for predicting risks of HCV infection and HCV/HIV co-infection	UNIVERSITY OF FLORIDA	2025-04-04
R01DA059234-02S1	Hemp-derived Cannabidiol for the treatment of cannabis use disorder in concentrate users: A double-blind placebo-controlled randomized trial	UNIVERSITY OF COLORADO	2025-04-04
R01AG074213	Perceived racism, cardiovascular disease risk, and neurocognitive aging	BOSTON UNIVERSITY MEDICAL CAMPUS	2025-04-07
R01AG074213-03S1	Perceived racism, cardiovascular disease risk, and neurocognitive aging	BOSTON UNIVERSITY MEDICAL CAMPUS	2025-04-07
R01AG074213-03S2	Perceived racism, cardiovascular disease risk, and neurocognitive aging	BOSTON UNIVERSITY MEDICAL CAMPUS	2025-04-07
F31AI184167	Developing Virus like Particles for HIV-1 Cure Strategy	EMORY UNIVERSITY	2025-04-08
T34GM136471	U-RISE Program at Fayetteville State University	FAYETTEVILLE STATE UNIVERSITY	2025-04-09
F31GM150277	Investigating the role of Polo-like kinase in regulating synaptonemal complex dynamics	JOHNS HOPKINS UNIVERSITY	2025-04-10
R01HG012216-03S1	Extensive multiplexing of protein nucleic-acid interactions to comprehensively study gene expression regulation from chromatin to mRNA degradation	COLUMBIA UNIV NEW YORK MORNINGSIDE	2025-04-10
R01HG012216-03S2	Extensive multiplexing of protein nucleic-acid interactions to comprehensively study gene expression regulation from chromatin to mRNA degradation	COLUMBIA UNIV NEW YORK MORNINGSIDE	2025-04-10
R01HG012271-03S1	Age-based genomic screening in newborns, infants, and children: a novel paradigm in public health genomics	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-10
R01HG012590-02S1	Davoli/Mita Diversity Supplement	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	2025-04-10
U01HG012051-04S1	Genomic control of gene regulatory networks governing early human lineage decisions	SLOAN-KETTERING INST CAN RESEARCH	2025-04-10
U01HG013276-02S1	EXposomic Profiling in Airway disease to uNravel Determinants of disease in Asthma (EXPAND-Asthma) Center	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-10
F31ES036437	The respiratory microbiome and its role in the host response to wood smoke	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-11
R01HG013773	Social, Genomic, and Epigenomic Drivers of Clopidogrel Response in Puerto Ricans	NORTHWESTERN UNIVERSITY AT CHICAGO	2025-04-14
R01HG013794	Improving PGS Prediction for Underrepresented Groups Through Transfer Learning	HENRY FORD HEALTH + MICHIGAN STATE UNIVERSITY HEALTH SCIENCES	2025-04-14
R25GM064118	Postbaccalaureate Research Education Program (PREP)	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2025-04-14
R25GM064120	MU PREP Scholars	UNIVERSITY OF MISSOURI-COLUMBIA	2025-04-14
R25GM066522	The University of Chicago PREP	UNIVERSITY OF CHICAGO	2025-04-14
R25GM066526	UofSC Postbaccalaureate Research Education Program	UNIVERSITY OF SOUTH CAROLINA AT COLUMBIA	2025-04-14
R25GM066567	Tufts Post-Baccalaureate Research Education Program	TUFTS UNIVERSITY BOSTON	2025-04-14
R25GM071745	UPenn Post Baccalaureate Research Education Program.	UNIVERSITY OF PENNSYLVANIA	2025-04-14
R25GM075149	PREP@UNM Competing Renewal	UNIVERSITY OF NEW MEXICO	2025-04-14
R25GM086256	UAB PREP Scholars Program	UNIVERSITY OF ALABAMA AT BIRMINGHAM	2025-04-14
R25GM086262	University of Michigan Postbaccalaureate Research Education Program (UM PREP)	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-04-14
R25GM089569	UNC PREP in the Biomedical Sciences	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-14
R25GM089571	Ohio State University Discovery PREP for Biomedical Research	OHIO STATE UNIVERSITY	2025-04-14
R25GM089614	Virginia Commonwealth University Postbaccalaureate Research Education Program	VIRGINIA COMMONWEALTH UNIVERSITY	2025-04-14
R25GM104552	UC Santa Cruz PREP	UNIVERSITY OF CALIFORNIA SANTA CRUZ	2025-04-14
R25GM109432	IPREP: IUPUI Graduate Preparation for the Biomedical and Behavioral Sciences	INDIANA UNIVERSITY INDIANAPOLIS	2025-04-14
R25GM113278	MUSC Post-Baccalaureate Research Education Program	MEDICAL UNIVERSITY OF SOUTH CAROLINA	2025-04-14
R25GM121212	UIC Portal to Biomedical Research Careers PREP (UIC PBRC-PREP)	UNIVERSITY OF ILLINOIS AT CHICAGO	2025-04-14
R25GM121220	Pathway to graduate study post-baccalaureate training program	UNIV OF MASSACHUSETTS MED SCH WORCESTER	2025-04-14
R25GM134978	OHSU PREP - Guiding Promising Underrepresented Post-Baccalaureates to be Successful Biomedical Scholars	OREGON HEALTH & SCIENCE UNIVERSITY	2025-04-14
R25GM140243	Colorado Preparation in Interdisciplinary Knowledge to Excel PREP	UNIVERSITY OF COLORADO DENVER	2025-04-14
R25GM140276	PREP @ UC Berkeley	UNIVERSITY OF CALIFORNIA BERKELEY	2025-04-14
R25GM144169	Post-Baccalaureate Research and Education Program (PREP) for Oklahoma	UNIVERSITY OF OKLAHOMA HLTH SCIENCES CTR	2025-04-14

R25GM148309	LSUHSC-New Orleans Postbaccalaureate Research Education Program in Biomedical Sciences	LSU HEALTH SCIENCES CENTER	2025-04-14
R25GM148311	University of Notre Dame Post-baccalaureate Research and Education Program	UNIVERSITY OF NOTRE DAME	2025-04-14
R25GM148314	University of Louisville Biomedical Integrative Opportunity for Mentored Experience Development -PREP (UL-BIOMED-PREP)	UNIVERSITY OF LOUISVILLE	2025-04-14
R25HG006682	Promoting Diversity, Equity, Inclusion, and Belonging in Genomic Research.	BROAD INSTITUTE, INC.	2025-04-14
R25HG006687	Expanding Opportunities in Genomic Research for Underrepresented Students	WASHINGTON UNIVERSITY	2025-04-14
R25HG009644	Summer Scholars in Genome Sciences & Medicine	DUKE UNIVERSITY	2025-04-14
R25HG010028	Summer Undergraduate and Postbacc Experiences in Genomic Medicine (SUPER-GM)	UNIVERSITY OF ALABAMA AT BIRMINGHAM	2025-04-14
R25HG012219	Educational Pathways to increase Diversity in Genomics (EDGE) at UNC Chapel Hill	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-14
R25HG012733	JAX Diversity Action Plan (DAP) Post-Baccalaureate Program in Genomics (gDAP)	JACKSON LABORATORY	2025-04-14
R25HG013857	Enhancing Diversity in Genomics Education and Research (EDGER)	HAMPTON UNIVERSITY	2025-04-14
F31DC021889	The Effect of Cochlear Synaptopathy on Auditory Nerve Responses in the Budgerigar	UNIVERSITY OF ROCHESTER	2025-04-15
F31DE033627	Spirochete Neutrophil Interactions Initiate Vascular Inflammation Promoting Aortic Endothelial Dysfunction	STATE UNIVERSITY OF NEW YORK AT BUFFALO	2025-04-15
K99DC021727	Neuroplasticity and early cochlear implant use	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	2025-04-15
K99DC022342	Hormone-Mediated Plasticity within Central Auditory Circuits	COLORADO STATE UNIVERSITY	2025-04-15
K99DC022343	Defining the role of MET components in vestibular hair cell maturation and gene therapy responsiveness	BOSTON CHILDREN'S HOSPITAL	2025-04-15
R01DE024748-08S1	Molecular and Developmental Analysis of Holoprosencephaly	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2025-04-15
R01EB024989-06S1	Detection of Emergent Mechanical Properties of Biologically Complex Cellular States	UNIVERSITY OF CALIFORNIA BERKELEY	2025-04-15
R01EB033179-03S1	Toward fast and deep imaging of living tissue with cellular resolution	CORNELL UNIVERSITY	2025-04-15
R01EB034279-02S1	Bottom-up, high-throughput prototyping of extracellular vesicle mimetics using cell-free synthetic biology	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-15
R03ES036327-01S1	Uncovering the Role of Histone Acetylation in Tetrabromobisphenol A-induced Developmental Toxicity during Zygotic Genome Activation	CLEMSON UNIVERSITY	2025-04-15
R21DE032798	Evaluation of a microbiota-sparing therapeutic concept for periodontal disease, involving removal of pathogenic Porphyromonas and Fusobacterium	TEXAS A&M UNIVERSITY HEALTH SCIENCE CTR	2025-04-15
R25GM113262	UMB Postbaccalaureate Research Education Program	UNIVERSITY OF MARYLAND BALTIMORE	2025-04-15
R25GM116690	Postbaccalaureate Research Education Program at UC Davis	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-15
F31AI176804	How ribosomal silencing promotes chronic infection of the gastric pathogen Helicobacter pylori	UNIVERSITY OF CALIFORNIA SANTA CRUZ	2025-04-17
F31AI181059	Rift Valley fever virus NSs protein interacts with LC3 family members to inhibit antiviral autophagy	VIRGINIA POLYTECHNIC INST AND ST UNIV	2025-04-17
F31AI181528	Assessing the role of SP140 in enhanced resistance to Cryptococcus neoformans	UNIVERSITY OF MINNESOTA	2025-04-17
F31AI186217	Regulation of B cell receptor avidity to organize antigen recognition	HARVARD MEDICAL SCHOOL	2025-04-17
F31AI186234	The Influence of Aging on Plasma Cell Function and Bone Marrow Competition	ALBERT EINSTEIN COLLEGE OF MEDICINE	2025-04-17
F31AI186410	Metatranslatomics enables functional profiling of microbial competition in the Salmonella-perturbed gut	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-17
F31AI186463	Discovery of new phage defense systems in Vibrio cholerae	HENRY FORD HEALTH + MICHIGAN STATE UNIVERSITY HEALTH SCIENCES	2025-04-17
F31AI186483	Elucidating RNA determinants for reovirus packaging	VANDERBILT UNIVERSITY	2025-04-17
F31AI186487	Genetic Modeling the Integration of Biological Sex, Immunity, and Metabolism	TEXAS A&M UNIVERSITY HEALTH SCIENCE CTR	2025-04-17
F31AI186499	Characterization of a sensor domain for cytoplasmic nucleic acid in the antiviral factor, SAMD9	UNIVERSITY OF TEXAS HLTH SCIENCE CENTER	2025-04-17
F31AI186506	Repurposing Drugs to Discover Novel Antifungals for Coccidioidomycosis	UNIVERSITY OF TEXAS SAN ANTONIO	2025-04-17
F31AI186614	PTPN1 and PTPN2 as targets to improve NK function against HIV	GEORGE WASHINGTON UNIVERSITY	2025-04-17
K99DA060951	Role of Anterior Cingulate Cortex Ensemble Regulation of Spinal Cord Excitability in Associative Opioid Analgesic Tolerance.	YALE UNIVERSITY	2025-04-17
R00DA052641	Sex differences in cholinergic regulation of nicotinic acetylcholine receptor modulation of local nucleus accumbens circuitry underlying motivation	UNIVERSITY OF ALABAMA AT BIRMINGHAM	2025-04-17
R00DA056842	Native Spirit: Culturally-grounded substance use prevention for Indigenous adolescents	ARIZONA STATE UNIVERSITY-TEMPE CAMPUS	2025-04-17
R01AI109139	Using bile salt metabolism to modulate CDI prophylaxis	UNIVERSITY OF NEVADA LAS VEGAS	2025-04-17
R01AI165656	Elucidating the molecular mechanisms of septin-dependent drug response to the antifungal caspofungin in the human pathogen Aspergillus fumigatus	VIRGINIA POLYTECHNIC INST AND ST UNIV	2025-04-17

R01AI168169	Defining the molecular interactions required for flavivirus genome packaging and virus assembly	PENNSYLVANIA STATE UNIVERSITY, THE	2025-04-17
R01AI171196	Phosphoarginine-linked protein quality control and stress responses in mycobacteria	UNIVERSITY OF DELAWARE	2025-04-17
R01AI173108	Understanding and leveraging immunometabolism to combat Clostridioides difficile infection	UNIVERSITY OF OKLAHOMA HLTH SCIENCES CTR	2025-04-17
R01AI173928	Triple-enriched metagenomics for robust resistome analysis	UNIVERSITY OF MINNESOTA	2025-04-17
R01AI174875	AAV Vectored Delivery of Broadly Neutralizing Antibodies with Optimal Innate Functionality Against HIV	MASSACHUSETTS GENERAL HOSPITAL	2025-04-17
R01AI178776	Spore germination pathway in Clostridioides difficile and its pharmacological intervention	UNIVERSITY OF NOTRE DAME	2025-04-17
R01AI178864	Kynurenine-dependent redox signaling at the interface between innate and adaptive immunity	UNIVERSITY OF ALABAMA AT BIRMINGHAM	2025-04-17
R01AI178875	Susceptibility and resistance of multidrug-resistant gram-negative bacteria to novel beta-lactam/beta-lactamase inhibitor combinations	BETH ISRAEL DEACONESS MEDICAL CENTER	2025-04-17
R01AI178925	Dendritic cell targeting by bacterial LysM proteins to suppress inflammation	UNIVERSITY OF COLORADO DENVER	2025-04-17
R01AI178947	γδTCR-dependent and independent differentiation of innate lymphoid cells	OKLAHOMA MEDICAL RESEARCH FOUNDATION	2025-04-17
R01AI178973	Translational Control of Host Environmental Stress Responses in Candida albicans	UNIVERSITY OF TEXAS HLTH SCIENCE CENTER	2025-04-17
R01AI178975	Structural Determinants of Permeation Barriers in Escherichia coli	UNIVERSITY OF VIRGINIA	2025-04-17
R01AI178992	The Variation of the NK Cell Receptome in Pemphigus	UNIVERSITY OF NORTH CAROLINA CHARLOTTE	2025-04-17
R01AI179046	Identifying Synergistic Rifabutin-Containing Combinations Against A. baumannii	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-04-17
R01AI179891	A Rapid Phenotypic Drug Susceptibility Testing System for Tuberculosis	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-04-17
R01AI181690	Spatial analysis of tissue immune responses in persistent HIV infection	MASSACHUSETTS GENERAL HOSPITAL	2025-04-17
R01AI182423	CD79A as a molecular switch regulating B cell activation	UNIVERSITY OF COLORADO DENVER	2025-04-17
R01DE031270-02S1	Molecular mechanisms mediating the soft tissue attachment to teeth	STANFORD UNIVERSITY	2025-04-17
R01DE031299-02S1	Small extracellular vesicles as biomarkers of prognosis and response to therapy in head and neck cancer	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-04-17
R01MD015920-03S1	Longitudinal Determinants of Thriving and Well-Being in Venezuelan Crisis Migrants	UNIVERSITY OF FLORIDA	2025-04-17
R01MD016278-03S1	Determining the Effects of Food Insecurity and Psychosocial Stress on Racial and Ethnic Disparities in Prenatal Nutrition and Preterm Birth Risk	COLUMBIA UNIVERSITY HEALTH SCIENCES	2025-04-17
R25EB027605	UTSA ESTEEMED Program	UNIVERSITY OF TEXAS SAN ANTONIO	2025-04-17
R25EB031572	ESTEEMED Scholars Program in Bioengineering at the University of Colorado Denver	UNIVERSITY OF COLORADO DENVER	2025-04-17
R25EB033075	Building Early Awareness and Research in Science (BEARS)	CALIFORNIA STATE UNIVERSITY SAN MARCOS	2025-04-17
R25EB033076	Call Me Doctor ESTEEMED Scholars Program at Clemson University	CLEMSON UNIVERSITY	2025-04-17
R25EB033077	ESTEEMED LEArning and Discovery through Engineering Research at Syracuse (LEADERS)	SYRACUSE UNIVERSITY	2025-04-17
R25EB035579	LSU ESTEEMED	LOUISIANA STATE UNIV A&M COL BATON ROUGE	2025-04-17
R25ES030240	EMPOWER 2.0 (Engaging Multi-Disciplinary Professional Opportunities for Women in Environmental Research)	GEORGIA STATE UNIVERSITY	2025-04-17
DP2AI171120-03S1	Crossing scales to predict and prevent bat virus zoonoses in a Madagascar ecosystem	UNIVERSITY OF CHICAGO	2025-04-18
DP2AI171120-03S2	Crossing scales to predict and prevent bat virus zoonoses in a Madagascar ecosystem	UNIVERSITY OF CHICAGO	2025-04-18
DP2AI171122-03S1	Parallel phenotyping to dissect genetic determinants of bacterial strain diversity	UNIVERSITY OF UTAH	2025-04-18
DP2AI177927-02S1	Dissecting the impact of immune environment on Candida albicans pathogenic potential in the gut	UNIVERSITY OF COLORADO DENVER	2025-04-18
F31AI162230	NK Cell Cytotoxicity Against Cryptococcus neoformans in Persons with Advanced HIV and Cryptococcal Meningitis	UNIVERSITY OF MINNESOTA	2025-04-18
P01AI091580-13S1	Defining the Unique Properties of the Distinct Signaling Machinery Used by the TCR	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-18
P01AI125180-08S1	Plasma Cells in Health and Disease	EMORY UNIVERSITY	2025-04-18
P01AI165380-03S1	Multi-Scale Evaluation and Mitigation of Toxicities Following Internal Radionuclide Contamination	NORTHWESTERN UNIVERSITY AT CHICAGO	2025-04-18
R01AI054423-20S1	Genetic requirements of Helicobacter pylori infection	FRED HUTCHINSON CANCER CENTER	2025-04-18
R01AI079178-12S1	Lymphatic regulation of lymph node function in lupus	HOSPITAL FOR SPECIAL SURGERY	2025-04-18
R01AI116946-09S1	The function of chemotactic signal transduction during colonization and disease	UNIVERSITY OF CALIFORNIA SANTA CRUZ	2025-04-18
R01AI118861-09S1	Innate immune-mediated control of pulmonary Legionella pneumophila infection	UNIVERSITY OF PENNSYLVANIA	2025-04-18
R01AI125524-09S1	Kinase Regulation of Nuclear Speckle Function and Splicing during Influenza Virus Infection	UNIVERSITY OF PENNSYLVANIA	2025-04-18

R01AI130020-06S1	Defining Mechanisms for Parasite-Driven Effects on Gamma-Herpesvirus Latency	UT SOUTHWESTERN MEDICAL CENTER	2025-04-18
R01AI130110-08S1	Mechanisms of innate resistance to virus infections	OHIO STATE UNIVERSITY	2025-04-18
R01AI139261-06S1	Decoding the clinical impact of the recent evolution of metronidazole resistance on Clostridium difficile infection.	TEXAS A&M UNIVERSITY HEALTH SCIENCE CTR	2025-04-18
R01AI139261-06S2	Diversity Supplement: Decoding the clinical impact of the recent evolution of metronidazole resistance on Clostridium difficile infection	TEXAS A&M UNIVERSITY HEALTH SCIENCE CTR	2025-04-18
R01AI148241-04S1	Iron independent role for yersiniabactin in Yersinia pestis	UNIVERSITY OF LOUISVILLE	2025-04-18
R01AI148300-04S1	The olfactory basis of locating nectar sugar sources in Aedes aegypti mosquitoes	UNIVERSITY OF WASHINGTON	2025-04-18
R01AI150762-04S1	Elucidating the path to type I IFNs in TB infection	MASSACHUSETTS GENERAL HOSPITAL	2025-04-18
R01AI151163-04S1	Neuroimmune Control of Allergic Immunity	MASSACHUSETTS GENERAL HOSPITAL	2025-04-18
R01AI155560-03S1	Coxiella survival mechanisms in the intracellular niche	UNIVERSITY OF NEBRASKA MEDICAL CENTER	2025-04-18
R01AI155653-04S1	Mechanisms of B cell responses to particulate antigens	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-04-18
R01AI155680-04S1	Cytomegalovirus (CMV), the gut barrier and immune dysfunction in HIV	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-18
R01AI155739-04S1	Soil epidemiology: a new tool for environmental surveillance of soil-transmitted helminth infections in endemic settings.	UNIVERSITY OF CALIFORNIA BERKELEY	2025-04-18
R01AI155915-04S1	Biogenesis of cyclic and phospholipid-linked enterobacterial common antigen	TEXAS A&M UNIVERSITY	2025-04-18
R01AI157445-05S1	Optimization of antimalarials targeting multiple life stages of the parasite	UNIVERSITY OF ILLINOIS AT CHICAGO	2025-04-18
R01AI158294-03S1	Program stem-like CD8 T cells to enhance antiviral immunity against chronic viral infection	UT SOUTHWESTERN MEDICAL CENTER	2025-04-18
R01AI160896-04S1	Role of the environmental sensor, AhR on colitis	UNIVERSITY OF SOUTH CAROLINA AT COLUMBIA	2025-04-18
R01AI162260-04S1	A multiscale approach for elucidating nuclear entry mechanisms of HIV-1 capsid	YALE UNIVERSITY	2025-04-18
R01AI162815-04S1	Negative regulation of innate immune signaling pathways by the selective autophagy receptor TAX1BP1	PENNSYLVANIA STATE UNIV HERSHEY MED CTR	2025-04-18
R01AI163196-03S1	Synergistic killing of bacterial pathogens by histones	UNIVERSITY OF CALIFORNIA-IRVINE	2025-04-18
R01AI164682-04S1	Understanding and manipulating chronic Helicobacter pylori to enhance treatment	UNIVERSITY OF CALIFORNIA SANTA CRUZ	2025-04-18
R01AI165519-03S1	Adaptation of vancomycin-resistant enterococci during bloodstream infection	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-04-18
R01AI165537-03S1	Relapsing malaria in Africa: mechanisms for persistence amid falciparum decline	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-18
R01AI165560-04S1	Next generation mosquito control through technology-driven trap development and artificial intelligence guided detection of mosquito breeding habitats	UNIVERSITY OF SOUTH CAROLINA AT COLUMBIA	2025-04-18
R01AI165638-02S1	Identifying HPV-host interactions using network-based analysis of preexisting transcriptomic data	UNIVERSITY OF ARIZONA	2025-04-18
R01AI167947-03S1	Pertussis inflammation is mediated by a balance between peptidoglycan recognition proteins-1 and -4	UNIVERSITY OF MARYLAND BALTIMORE	2025-04-18
R01AI168916-02S1	Infection-Dependent Vulnerabilities of Gram-negative Bacterial Pathogens	UNIVERSITY OF COLORADO	2025-04-18
R01AI169460-03S1	Mapping spatiotemporal dynamics during enterovirus infection across cells and tissues	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-18
R01AI170725-03S1	New insights into the functional diversity of the hepatic antiviral T cell response during hepacivirus infection in vivo	ALBERT EINSTEIN COLLEGE OF MEDICINE	2025-04-18
R01AI170777-02S1	Identifying roles for hepatic myeloid cells in the induction and maintenance of anti-Plasmodium liver-resident memory CD8 T cells	SEATTLE CHILDREN'S HOSPITAL	2025-04-18
R01AI170835-03S1	Genome-wide CRISPR-Cas9 screens in insect cells to characterize insecticidal toxins	BOSTON CHILDREN'S HOSPITAL	2025-04-18
R01AI170840-03S1	mRNA alternative polyadenylation in B cell development	UNIVERSITY OF CALIFORNIA-IRVINE	2025-04-18
R01AI171200-03S1	Innate immune recognition and response to Rift Valley fever virus	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-04-18
R01AI172607-03S1	Amplifying and Redirecting CMV-specific CD8 T cells to provide sustained control of HIV infection	ALBERT EINSTEIN COLLEGE OF MEDICINE	2025-04-18
R01AI173199-02S1	Breastmilk antibodies regulate neonatal immunity to the microbiota	FRED HUTCHINSON CANCER CENTER	2025-04-18
R01AI173244-02S1	Mechanisms of hypervirulent Klebsiella pneumoniae gastrointestinal colonization and dissemination	WAKE FOREST UNIVERSITY HEALTH SCIENCES	2025-04-18
R01AI174519-02S1	Sex Differences in NK Cells Mediated by X-linked UTX	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-04-18
R01AI175078-02S1	Pyroptosis maintains the integrity of a granuloma	DUKE UNIVERSITY	2025-04-18
R01AI175079-02S1	Esophageal gland-mediated immune evasion by the human parasite Schistosoma mansoni	UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON	2025-04-18
R01AI175614-02S1	The role of tyrosine metabolism in tuberculosis pathogenesis	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-18
R01AI176390-02S1	Harnessing iron acquisition to hinder enterobacterial pathogenesis	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-18

R01AI177635-02S1	Hijacking Plasmodium ubiquitin-proteasome system to defeat drug resistance	WEILL MEDICAL COLL OF CORNELL UNIV	2025-04-18
R01AI178908-02S1	The role of a bifunctional mucinase in modulating personalized gut microbiota-Vibrio cholerae interactions during infection	UNIVERSITY OF PENNSYLVANIA	2025-04-18
R01MD016426-03S1	Provider Experiences with Puerto Rico Medicaid Following Multiple Disasters	UNIVERSITY OF HAWAII AT MANOA	2025-04-18
R01MH130609-03S1	Dysregulation of dopamine receptors in the basal ganglia in OCD and tic disorders: Positron Emission Tomography with [11C]-PHNO	YALE UNIVERSITY	2025-04-18
R37AI071727-18S1	Mechanisms that determine subcellular sites of HIV-1 assembly	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-04-18
U01AI166309-03S1	Functional dynamics of TB granuloma architecture - Diversity Supplement for Kelley J. Martinez	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-18
U19AI077439-17S1	Immune-driven Airway Epithelial Dysfunction in Muco-obstructive Asthma	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-18
R25EB027606	Motivating Innovation and Research Achievement (MIRA)	WASHINGTON STATE UNIVERSITY	2025-04-21
R25EB031570	University of Georgia (UGA) ESTEEMED: Mentored Experiential Research to Promote Diversity in Biomedical Engineering and Science	UNIVERSITY OF GEORGIA	2025-04-21
R25EB031571	NC A&T ESTEEMED Program	NORTH CAROLINA AGRI & TECH ST UNIV	2025-04-21
R25EB033070	VT-ESTEEMED	VIRGINIA POLYTECHNIC INST AND ST UNIV	2025-04-21
R25EB033080	BiOengineering Research Education to AcceLerate Innovation in STEM	CLARKSON UNIVERSITY	2025-04-21
P01CA214091-08S1	Noncoding RNAs in gamma-Herpesvirus Biology and AIDS Malignancies	UNIVERSITY OF FLORIDA	2025-04-22
P01CA214091-08S2	Noncoding RNAs in gamma-Herpesvirus Biology and AIDS Malignancies	UNIVERSITY OF FLORIDA	2025-04-22
R01CA247943-04S1	Aberrant STAT Function in CEBPA-mutant Acute Myeloid Leukemia	OREGON HEALTH & SCIENCE UNIVERSITY	2025-04-22
R01NR014855-08S1	Multilevel Panel Study of Effects of Changes in Nursing on Health Equity and Patient Outcomes	UNIVERSITY OF PENNSYLVANIA	2025-04-22
R37MH128729-03S1	Project STRIVE (STudents RIsing above) - Offsetting the health and mental health costs of resilience	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-04-22
DP1MH132709-03S1	Precision editing of neural circuits using engineered electrical synapses	DUKE UNIVERSITY	2025-04-23
R00MH122663-04S1	The role of context in sleep-related memory reactivation in humans	UNIVERSITY OF CALIFORNIA-IRVINE	2025-04-23
R01MH120776-05S1	Sleep Disturbance and Emotion Regulation Brain Dysfunction as Mechanisms of Neuropsychiatric Symptoms in Alzheimer's Dementia	STANFORD UNIVERSITY	2025-04-23
R01MH121449-05S1	Neural Mechanisms of Reading Dysfunction in Schizophrenia	COLUMBIA UNIVERSITY HEALTH SCIENCES	2025-04-23
R01MH121601-05S1	High-throughput modeling of autism risk genes using zebrafish	CALIFORNIA INSTITUTE OF TECHNOLOGY	2025-04-23
R01MH121617-05S1	Mobile Measures of Threat Sensitivity for Cross-sectional and Longitudinal Assessment	MCLEAN HOSPITAL	2025-04-23
R01MH124526-05S1	Enhancing HIV assisted contact tracing in Malawi through blended learning: An Implementation Science Study	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-23
R01MH126083-04S1	Glutamatergic adaptation to stress as a mechanism for anhedonia and treatment response with ketamine	EMORY UNIVERSITY	2025-04-23
R01MH126762-04S1	Intimate Partner Violence and HIV Prevention among Sexual Minority Men	SAN DIEGO STATE UNIVERSITY	2025-04-23
R01MH127265-04S1	Neurobehavioral mechanisms of social isolation and loneliness in serious mental illness	MASSACHUSETTS GENERAL HOSPITAL	2025-04-23
R01MH128198	Aging, Major Life Transitions, and Suicide Risk	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-04-23
R01MH128198-04S1	Aging, Major Life Transitions, and Suicide Risk	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-04-23
R01MH128246-03S1	Neurobiological Underpinnings of Avoidant/Restrictive Food Intake Disorder in Adults	MASSACHUSETTS GENERAL HOSPITAL	2025-04-23
R01MH128286-03S2	Comparing sensorimotor and association cortex contributions in late life depression	WASHINGTON UNIVERSITY	2025-04-23
R01MH128306-03S1	Testing a Memory-Based Hypothesis for Anhedonia	UNIVERSITY OF CALIFORNIA-IRVINE	2025-04-23
R01MH128377-03S1	Neural Markers of Treatment Mechanisms and Prediction of Treatment Outcomes in Social Anxiety	BOSTON UNIVERSITY (CHARLES RIVER CAMPUS)	2025-04-23
R01MH129185-03S1	Trends in Incidence and Prevalence of HIV Diagnoses in a Jail Population in the Southern United States	UT SOUTHWESTERN MEDICAL CENTER	2025-04-23
R01MH129436-02S1	Learning novel structure across time and sleep	UNIVERSITY OF PENNSYLVANIA	2025-04-23
R01MH132022-03S1	Next generation transcranial ultrasound-based neuromodulation using phase shift nanoemulsions	VANDERBILT UNIVERSITY MEDICAL CENTER	2025-04-23
R37MH128729-03S2	Project STRIVE (STudents RIsing above) - Offsetting the health and mental health costs of resilience	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-04-23
U01HD115257	Promoting Color Brave Conversations in Families: A Public Health Strategy to Advance Racial Equity	TULANE UNIVERSITY OF LOUISIANA	2025-04-23
R01CA174869-08S1	Regulation of Tumor Invasion and Metastasis by Matrix Stiffness	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-24
R01EB033913	A Novel Spray-On Sensing Platform Technology that Enables Wearable Visual Monitoring of Physiological Data and Environmental Exposure	UNIVERSITY OF TEXAS ARLINGTON	2025-04-24

R01EB033918	A New Multimodal Molecular Imaging Approach to Guide Intra-Operative Tumor Resection and Post-Operative Treatment Planning	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-04-24
R01EB033918-02S1	A New Multimodal Molecular Imaging Approach to Guide Intra-Operative Tumor Resection and Post-Operative Treatment Planning	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-04-24
R01EB033919	Bioengineering probiotic bacterium contrast agents for monitoring of inflammation using multispectral optoacoustic tomography	UNIVERSITY OF MISSOURI-COLUMBIA	2025-04-24
R01EB034086	Ionic Liquid-Coated NIR-II Polymer Conjugates as Targeted Brain Theranostics	OHIO STATE UNIVERSITY	2025-04-24
R01MH121520-04S1	Neural mechanisms of perceptual abnormalities and their malleability in bodydysmorphic disorder	CENTRE FOR ADDICTION AND MENTAL HEALTH	2025-04-24
R01MH126236-04S1	Preclinical Assays of Hippocampal-Prefrontal Cortical Circuit Engagement for Application in Therapeutic Development	UNIVERSITY OF FLORIDA	2025-04-24
R01MH127162-03S1	2/5 Biomarkers/Biotypes, Course of Early Psychosis and Specialty Services (BICEPS)	UNIVERSITY OF CHICAGO	2025-04-24
R01MH127577-04S1	ASHA Bangladesh--An Integrated Intervention to Address Depression in Low Income Rural Women	UNIV OF MASSACHUSETTS MED SCH WORCESTER	2025-04-24
R01MH128746-03S1	Cortical plasticity during reinforcement learning - Diversity Supplement	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-24
R01MH129495-03S1	Extracellular vesicles as biomarkers of trauma exposure and PTSD risk	UNIVERSITY OF COLORADO DENVER	2025-04-24
R01NS123051-03S1	Single stage surgical intervention for treatment of severe traumatic brain injury	UNIVERSITY OF OKLAHOMA	2025-04-24
R37CA247994-04S1	Mitochondrial lateral transfer during metastasis	UNIVERSITY OF UTAH	2025-04-24
R37CA258261-03S1	Defining the Role of Renal Gluconeogenesis in Renal Cell Carcinoma	YALE UNIVERSITY	2025-04-24
T32GM135744	IMSD: An Initiative to Maximize Student Development in Biomedical Research at MU	UNIVERSITY OF MISSOURI-COLUMBIA	2025-04-24
T32GM135746	IMSD at Stony Brook University: Maximizing Excellence in Research for Graduate Education	STATE UNIVERSITY NEW YORK STONY BROOK	2025-04-24
T32GM135751	IMSD at the University of Massachusetts Chan Medical School	UNIV OF MASSACHUSETTS MED SCH WORCESTER	2025-04-24
T32GM139779	University of Arizona's Initiative for Maximizing Student Development (IMSD)	UNIVERSITY OF ARIZONA	2025-04-24
T32GM139785	IMSD at Rush University	RUSH UNIVERSITY MEDICAL CENTER	2025-04-24
T32GM139800	Initiative for Maximizing Student Development (IMSD) at Vanderbilt	VANDERBILT UNIVERSITY	2025-04-24
T32GM139804	IMSD at Rutgers - New Brunswick	RUTGERS BIOMEDICAL AND HEALTH SCIENCES	2025-04-24
T32GM139805	IMSD at the University of Utah (IMSD@U2)	UNIVERSITY OF UTAH	2025-04-24
T32GM139807	IMSD at Wayne State University	WAYNE STATE UNIVERSITY	2025-04-24
T32GM144856	Initiative to Maximize Student Development in Translational Medicine	COLORADO STATE UNIVERSITY	2025-04-24
T32GM144880	Georgetown University Initiative for Maximizing Student Development (IMSD)	GEORGETOWN UNIVERSITY	2025-04-24
T32GM144920	Initiative for Maximizing Student Development at University at Buffalo	STATE UNIVERSITY OF NEW YORK AT BUFFALO	2025-04-24
T32GM144926	IMSD@Brown	BROWN UNIVERSITY	2025-04-24
T32GM144951	UMB IMSD	UNIVERSITY OF MARYLAND BALTIMORE	2025-04-24
T32GM148391	IMSD at Emory University	EMORY UNIVERSITY	2025-04-24
T32GM148403	VCU Initiative for Maximizing Student Development Program (IMSD)	VIRGINIA COMMONWEALTH UNIVERSITY	2025-04-24
T32GM148405	MAXIMIZING STUDENT DIVERSITY IN THE BIOMEDICAL SCIENCES AT WASHINGTON UNIVERSITY	WASHINGTON UNIVERSITY	2025-04-24
T32GM148410	IMSD at Dartmouth College	DARTMOUTH COLLEGE	2025-04-24
T32GM148752	IMSD at UT Health San Antonio	UNIVERSITY OF TEXAS HLTH SCIENCE CENTER	2025-04-24
T32GM152395	The University of Chicago Initiative for Maximizing Student Development (IMSD)	UNIVERSITY OF CHICAGO	2025-04-24
T32GM152775	Critical Analysis of Data-Rich Networks for Biomedical Scientists in Training.	UNIVERSITY OF NEBRASKA MEDICAL CENTER	2025-04-24
T32GM152779	UNC Initiative for Maximizing Student Development	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-24
T32GM152782	Initiative for Maximizing Student Development(IMSD)	UNIV OF ARKANSAS FOR MED SCIS	2025-04-24
T32GM152796	The Academy at MD Anderson UTHealth Houston Graduate School - Maximizing Opportunities for Training, Development, and Community	UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON	2025-04-24
T32GM156666	IMSD@UNTHSC	UNIVERSITY OF NORTH TEXAS HLTH SCI CTR	2025-04-24
T32GM156669	Initiative for Maximizing Student Development at Loma Linda University	LOMA LINDA UNIVERSITY	2025-04-24
T32GM156671	UCSF IMSD	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-24
T32GM156676	Virginia Tech Initiative to Maximize Student Development	VIRGINIA POLYTECHNIC INST AND ST UNIV	2025-04-24
U54MH118919-05S1	Sex Differences in Major Depression: Impact of Prenatal Stress-Immune and Autonomic Dysregulation	MASSACHUSETTS GENERAL HOSPITAL	2025-04-24
UM1MH130981-03S1	Evolutionary Pathways of Memory: Multiomic Analysis of the Entorhinal Cortex across Mammals.	ALLEN INSTITUTE	2025-04-24

UM1MH130981-03S2	Functionally guided adult whole brain cell atlas in human and NHP	ALLEN INSTITUTE	2025-04-24
UM1MH130981-03S3	Functionally guided adult whole brain cell atlas in human and NHP	ALLEN INSTITUTE	2025-04-24
F31DK139760	Mechanisms and functional role of mitochondria in eosinophilic esophagitis	TEMPLE UNIV OF THE COMMONWEALTH	2025-04-25
F31DK141124	The Role of Kidney-derived APOM in S1P-mediated glomerular injury	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	2025-04-25
F31DK141249	Investigating the roles and dynamics of the endoplasmic reticulum during paligenosis and metaplasia formation	BAYLOR COLLEGE OF MEDICINE	2025-04-25
P01CA254867	Determining and targeting mechanisms controlling cancer cell division	STANFORD UNIVERSITY	2025-04-25
P01CA254867-03S1	Determining and targeting mechanisms controlling cancer cell division	STANFORD UNIVERSITY	2025-04-25
P2CHD041023-24S1	Minnesota Population Center	UNIVERSITY OF MINNESOTA	2025-04-25
R01AR074417-04S2	Diversity Supplement for Rohda Yase	UNIVERSITY OF WASHINGTON	2025-04-25
R01AR075914-05S1	Molecular mechanisms of telomere function in muscle stem cells	UNIVERSITY OF PENNSYLVANIA	2025-04-25
R01AR078414-04S1	Studies on gut microbiome-joint connections in arthritis	UNIVERSITY OF COLORADO DENVER	2025-04-25
R01AR079184-04S1	Biomechanical and Biological Predictors of Cartilage Health Following Meniscus Injury	DUKE UNIVERSITY	2025-04-25
R01AR079189-04S1	Modulation of local adenosine signaling to attenuate fracture pain	DUKE UNIVERSITY	2025-04-25
R01AR079220-04S1	Circadian Clock and Muscle Health	UNIVERSITY OF FLORIDA	2025-04-25
R01AR080034-03S1	Functional Dissection of Regulatory Myeloid Cells in Microbe-Immune Crosstalk in Skin	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-25
R01CA269813	Impact of extracellular glutathione catabolism on triple-negative breast cancer	UNIVERSITY OF ROCHESTER	2025-04-25
R01CA269813-03S2	Impact of extracellular glutathione catabolism on triple-negative breast cancer	UNIVERSITY OF ROCHESTER	2025-04-25
R01HD101642-04S1	Postnatal Oxytocin Treatment and Cognitive Function in Fragile X	UNIVERSITY OF CALIFORNIA-IRVINE	2025-04-25
R01HD104185-03S1	Understanding the Development of Social Disconnection in Youth	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-25
R01HD109232-02S1	The Role of Chibby Family Members in Spermatogenesis and Male Fertility	STATE UNIVERSITY NEW YORK STONY BROOK	2025-04-25
R01HD109326-02S1	THE ROLE OF MESENCHYMAL PROGENITOR CELLS IN ABNORMAL UTERINE REPAIR	YALE UNIVERSITY	2025-04-25
R01MH052716-28S1	Neuroinflammation, Epigenetics and Male Vulnerability	UNIVERSITY OF MARYLAND BALTIMORE	2025-04-25
R01MH106460-08S1	Consequences of HDAC2 inhibition in VTA-NAc circuitry	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-04-25
R01MH125800-04S1	Precursors of Anxiety: The Role of Lateralized Brain Activation and Maternal Sensitivity	WASHINGTON STATE UNIVERSITY	2025-04-25
R01MH125905-03S1	Effects of parental history of suicidal behavior on middle/late childhood: Longitudinal assessment of early markers of suicide risk	UNIVERSITY OF ROCHESTER	2025-04-25
R01MH126960-04S1	Convergent mechanisms for neurodevelopmental disorder genes	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-04-25
R01MH128293-02S1	Thalamo-prefrontal circuit maturation during adolescence	NEW YORK STATE PSYCHIATRIC INSTITUTE DBA RESEARCH FOUNDATION FOR MENTAL HYGIENE	2025-04-25
R01MH128928-04S1	Social and Biological Mechanisms Driving the Intergenerational Impact of War on Child Mental Health: Implications for Developing Family-Based Interventions	BOSTON COLLEGE	2025-04-25
R01MH129374-03S1	Parent interpretation bias as a key mechanism of intergenerational transmission of anxiety	MCLEAN HOSPITAL	2025-04-25
R01MH129457-02S1	Towards a reliable and valid assessment of preteen suicidal thoughts and behavior	BROWN UNIVERSITY	2025-04-25
R01MH129634-03S1	Parent-child proximity and emerging psychopathology	VANDERBILT UNIVERSITY	2025-04-25
R01MH130007-03S1	Parent-to-child anxiety transmission in early childhood: Capturing in-the-moment mechanisms through emotion modeling and biological synchrony	PENNSYLVANIA STATE UNIVERSITY, THE	2025-04-25
R01MH130007-03S2	Understanding the Interplay between Parent and Child Contributions in Parent-Child Anxiety Transmission	PENNSYLVANIA STATE UNIVERSITY, THE	2025-04-25
R01MH130591-03S1	Mapping Neural Circuit Activity Mediating MDMA's Prosocial Effect	STANFORD UNIVERSITY	2025-04-25
R01MH134119-02S1	Phosphodiesterases govern nuclear cAMP signaling for gene expression	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-25
R37AR061402-13S1	Hox-Regulated MSCs in Skeletal Development, Growth and Fracture Healing	UNIVERSITY OF WISCONSIN-MADISON	2025-04-25
T32GM135741	Initiative for Maximizing Student Development at the University of California, Davis.	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-25
T32GM144891	IMSD at Indiana University School of Medicine through Inclusive Biomedical Research Training Program	INDIANA UNIVERSITY INDIANAPOLIS	2025-04-25
T32GM148295	IMSD at the University of Rochester	UNIVERSITY OF ROCHESTER	2025-04-25
T32GM148393	IMSD at the University of Texas at San Antonio	UNIVERSITY OF TEXAS SAN ANTONIO	2025-04-25
T32GM152386	MUSC IMSD	MEDICAL UNIVERSITY OF SOUTH CAROLINA	2025-04-25
T32GM152396	Weill Cornell Initiative for Maximizing Student Development	WEILL MEDICAL COLL OF CORNELL UNIV	2025-04-25
T32GM156689	IMSD AT HUNTER COLLEGE, CUNY	HUNTER COLLEGE	2025-04-25
F31DK130581	F31 Mulero Russe	GEORGIA INSTITUTE OF TECHNOLOGY	2025-04-28

F31DK131890	Circadian Regulation of In Vitro Differentiated Adipocytes	DARTMOUTH COLLEGE	2025-04-28
F31DK132916	Glomerulus on a Chip: A Model to Study Glomerular Hyperfiltration	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	2025-04-28
F31DK132918	Estrogen Signaling in the Ventromedial Hypothalamus Modulates Adipose Tissue Metabolic Adaptation	UNIVERSITY OF ILLINOIS AT CHICAGO	2025-04-28
F31DK134088	Ceramides as Novel Mediators of Tubular Metabolic Dysfunction Driving Kidney Injury	UNIVERSITY OF UTAH	2025-04-28
F31DK134157	Role of Central Neurotensin Signaling in the Ventral Tegmental Area for Ingestive Behavior and Body Weight	MICHIGAN STATE UNIVERSITY	2025-04-28
F31DK134158	The Role of Arginine Transport on Pancreatic Alpha Cell Proliferation and Function	VANDERBILT UNIVERSITY	2025-04-28
F31DK134160	A mechanism of lipid accumulation in brown adipose tissue	UNIVERSITY OF PENNSYLVANIA	2025-04-28
F31DK134173	Elucidating the role of nonessential amino acid metabolism in diabetic skin wounds	UNIVERSITY OF CALIFORNIA-IRVINE	2025-04-28
F31DK136205	Utility and feasibility of activity type to augment consumer wearable-based physical activity energy expenditure prediction equations using heartrate and movement in children	UNIVERSITY OF SOUTH CAROLINA AT COLUMBIA	2025-04-28
F31DK136228	Mechanistic and Therapeutic Role of the TLR4 Signaling Pathway in T1D	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-28
F31DK136330	Role of GPER in Obesity and Lipid Metabolism.	UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR	2025-04-28
F31DK136333	Exploring the role and mechanisms of action of UC pouchitis-associated pathobionts (PAP) to gain insights into the etiopathogenesis of Inflammatory Bowel Diseases	UNIVERSITY OF CHICAGO	2025-04-28
F31DK136335	Examining the role of defective oxidative phosphorylation in the normal and diseased prostate	UNIVERSITY OF WISCONSIN-MADISON	2025-04-28
F31DK137415	Investigating how xenobiotics interact with phages to shift energy balance	MEDICAL COLLEGE OF WISCONSIN	2025-04-28
F31DK137439	Targeting Inflammation to Improve FGF23-mediated Mineral Metabolism in CKD	INDIANA UNIVERSITY INDIANAPOLIS	2025-04-28
F31DK137440	Elucidating the Role of the Rnf20 Histone Modifier in Pancreatic Beta Cell Function and Senescence	UNIVERSITY OF ALABAMA AT BIRMINGHAM	2025-04-28
F31DK137538	Evaluating the Role of Human Obesity Genes in Specific Neuronal Populations in vivo by CRISPRi	UNIVERSITY OF CALIFORNIA BERKELEY	2025-04-28
F31DK138544	The role of LRRK2 in pancreatic beta cell responses to inflammatory damage	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-04-28
F31DK138621	Role of Gut Protist Derived Compounds on Dietary Antigen Presenting Dendritic Cells in Celiac Disease	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-04-28
F31DK138751	Investigating podocyte-parietal epithelial cell communication through intercellular bridges in kidney disease	STATE UNIVERSITY NEW YORK STONY BROOK	2025-04-28
F31DK138794	Linking GATA2 deficiency to innate immune signaling	UNIVERSITY OF WISCONSIN-MADISON	2025-04-28
K00ES036895	The ABCD Study and Brain Health: Navigating Environmental Hazards and the Quest for Neurodevelopmental Intersectional Health Equity	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-04-28
K99EB032749	Wearable RF-EEG Cap for closed loopTMS/fMRI/EEG Applications	MASSACHUSETTS GENERAL HOSPITAL	2025-04-28
R01CA167065-08S1	Defining mechanisms of gammaherpesvirus-driven genomic instability in B cells	UNIV OF ARKANSAS FOR MED SCIS	2025-04-28
R01CA221346-07S1	Improving cell-based immunotherapy for solid tumors using mechanical modulation	CORNELL UNIVERSITY	2025-04-28
R01CA252827-02S1	Supplemental Request for Mechanical Modulation of Cell Migrations by DNA Nanoassemblies	KENT STATE UNIVERSITY	2025-04-28
R01CA259192-04S1	Improving our understanding of breast cancer mortality disparities through recurrence: a multi-level approach among women in Georgia	EMORY UNIVERSITY	2025-04-28
R01CA259384-04S1	Understanding the role of TP53 mutation in genetic susceptibility to ovarian cancer	UNIVERSITY OF WASHINGTON	2025-04-28
R01CA263324-03S1	Defining the role of cytomegalovirus in glioblastoma therapies	BROWN UNIVERSITY	2025-04-28
R01EB033917	Pericyte reprogramming in fibrosis	YALE UNIVERSITY	2025-04-28
R01EB035543	Theory Assisted Design, Synthesis and Biological Activity of Bacteria-Targeting Nanostructures	UNIVERSITY OF NEBRASKA MEDICAL CENTER	2025-04-28
R01ES033054-04S1	Impact of pre- and postnatal chemical mixture exposures on child neurobehavior and neuroimaging	UNIVERSITY OF PENNSYLVANIA	2025-04-28
R01HG012413-03S1	Enzymeless, controlled electrostatic ratcheting in solid-state nanopores	COLUMBIA UNIV NEW YORK MORNINGSIDE	2025-04-28
R01MD019690	Effectiveness of a multilevel integrated intervention for LDCT lung cancer screening and smoking cessation among African Americans	LSU HEALTH SCIENCES CENTER	2025-04-28
R01MD020109	Community Health Information Education Forum (CHIEF)	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2025-04-28
R01MH068542-23S1	Circuits underlying overgeneralization	NEW YORK STATE PSYCHIATRIC INSTITUTE DBA RESEARCH FOUNDATION FOR MENTAL HYGIENE, INC	2025-04-28
R01MH085739-13S1	Timing, Reward Processing and choice	OHIO STATE UNIVERSITY	2025-04-28
R01MH120314-05S1	Neural pathways linking early adversity and preschool psychopathology to adolescent mental health	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-28

R01MH125000-05S1	Microglial remodeling of the extracellular matrix in memory circuits	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-28
R01MH128905-03S1	Examining the impact of menstrual hygiene management on academic achievement and mental health outcomes among school-going adolescent girls in Uganda	WASHINGTON UNIVERSITY	2025-04-28
R01MH132018	The role of excitatory VTA projections in novelty-dependent behavior	LOUISIANA STATE UNIV A&M COL BATON ROUGE	2025-04-28
R01MH133608-02S1	Serotonergic modulation of the circuits and cell-types of the lateral habenula	BOSTON UNIVERSITY MEDICAL CAMPUS	2025-04-28
R01MH134791	Brain network and cell-type elucidation of molecular dysregulations in bipolar disorder suicide	UNIVERSITY OF TEXAS AT AUSTIN	2025-04-28
R15MH113045-02S1	Cognitive and Contextual Factors in Suicide Ideation Persistence in Adolescents	WESTERN KENTUCKY UNIVERSITY	2025-04-28
R21MH135326-02S1	Functional circuit dissection of the Hcrt system	CENTRAL MICHIGAN UNIVERSITY	2025-04-28
R25EB036412	The Mississippi ESTEEMED Scholars Program	UNIVERSITY OF MISSISSIPPI	2025-04-28
R25EB036422	Cultivating Pathways to Research in Biomedical Engineering	UNIVERSITY OF ARIZONA	2025-04-28
R25EB036584	BIOMEDICAL ENGINEERING SUPERHEROES: Health Science, Engineering, and Data Science Elementary Curriculum Development & Outreach Program	UNIVERSITY OF TEXAS SAN ANTONIO	2025-04-28
R35ES030396-06S1	Excision Repair of Environmental Telomere Damage	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-04-28
R36MH135609	An intersectional approach to transgender and/or nonbinary college student mental health: The role of gender identity, race/ethnicity, socioeconomic status, and campus policy	HARVARD SCHOOL OF PUBLIC HEALTH	2025-04-28
R36MH135619	Transcriptomic contributions to the development and evolution of the human cerebral cortex	UNIVERSITY OF CALIFORNIA BERKELEY	2025-04-28
R36MH136790	Characterization of Fragile X Syndrome 3D Cortical Organoids	UNIVERSITY OF WISCONSIN-MADISON	2025-04-28
R36MH136796	Functional and molecular organization of lateral septum in threat processing	HARVARD MEDICAL SCHOOL	2025-04-28
R36MH136806	Mitochondrial Defects in 22q11.2 Deletion Using a Human-Derived Neuronal Stem Cell Model	EMORY UNIVERSITY	2025-04-28
R37CA271172-03S1	Effect of inflammation on JAK2 mutant evolution in the hematopoietic system: mathematical models and experiments	UNIVERSITY OF CALIFORNIA-IRVINE	2025-04-28
R37CA276215-02S1	Sustainability determinants of an intervention to identify clinical deterioration and improve childhood cancer survival in low-resource hospitals	ST. JUDE CHILDREN'S RESEARCH HOSPITAL	2025-04-28
R44MH123368-05S1	The Development and Systematic Evaluation of an AI-Assisted Just-in-Time-Adaptive-Intervention for Improving Child Mental Health	COLLIGA APPS CORP.	2025-04-28
U01MH125062-04S1	2/2 TRANS-ANCESTRY GENOMIC ANALYSIS OF OBSESSIVE COMPULSIVE DISORDER	BAYLOR COLLEGE OF MEDICINE	2025-04-28
DP1DK126160-04S1	Mitochondrial Metabolite Compartmentalization in Health and Disease	BETH ISRAEL DEACONESS MEDICAL CENTER	2025-04-29
DP1DK130640-04S1	Integrative approaches to dissection of endocrine communication	UNIVERSITY OF CALIFORNIA-IRVINE	2025-04-29
F31DK138784	THE ROLE OF CORTICOTROPHIN RELEASING FACTOR RECEPTOR 1 NEURONS IN THE BED NUCLEUS OF THE STRIA TERMINALIS IN MODULATING WEIGHT HOMEOSTASIS	BAYLOR COLLEGE OF MEDICINE	2025-04-29
F31DK138790	Hepatic Steatosis Induced by Bioactive Lipids	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-04-29
F31DK138803	Role of hepatic ploidy populations in liver injury and compensatory regeneration after acetaminophen overdose	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-04-29
F31HG012892	Advancing Epigenetic Sequencing Through Solid-Phase Enzymatic Approaches	UNIVERSITY OF PENNSYLVANIA	2025-04-29
F31MD017471	Outlining Shadows of Structural Racism Using Publicly Available Social Determinants of Health Data	UNIV OF MASSACHUSETTS MED SCH WORCESTER	2025-04-29
F31MD017957	Examining Perceived Familial and Self-Endorsement of Marianismo Cultural Script Discrepancies as Mental Health Risk Factors in Latina Americans	UNIVERSITY OF HOUSTON	2025-04-29
F31MD018535	Evaluating Multilevel Factors that Predict Physical Activity Among Latinos with Chronic Spine Pain: A Mixed-Methods Study	SAN DIEGO STATE UNIVERSITY	2025-04-29
F31MD018926	Understanding the role of emotion regulation flexibility in the association between daily stressors and emotional disorder symptoms in ethnic minority college students	UNIVERSITY OF UTAH	2025-04-29
F31MD018943	Pathways linking childhood and intergenerational trauma at the US-Mexico border with cardiovascular health.	UNIVERSITY OF ARIZONA	2025-04-29
F31MD019216	The Application of a Theoretical Framework to Assess the Acceptability of a Health-Related Social Needs Screening Tool Among Black Patients In New York City	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	2025-04-29
F31MD019996	Advancing Perinatal Health Equity through a Community-engaged Model of Healthcare Services	UNIVERSITY OF CALIFORNIA BERKELEY	2025-04-29
F31MD020240	Developing Racially Equitable post-release supervision Assignment guidelines to prevent overdose and suicide Mortality among formerly incarcerated people (DREAM)	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-29
F31MD020261	Understanding the Macrosocial Drivers of Cardiovascular Health in the Rural South	UNIVERSITY OF CALIFORNIA BERKELEY	2025-04-29

F31MD020275	Investigating Breast Cancer Outcomes in Haitian Immigrants	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	2025-04-29
F31MH132287	Deciphering the role of VTA dopaminergic signaling in memory consolidation during sleep	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-04-29
K00MH136687	Ventral Pallidal Circuits Governing Approach/Avoidance Conflict	UNIVERSITY OF PUERTO RICO MED SCIENCES	2025-04-29
K99MD018451	Advancing Indigenous Cancer Health Equity through a Community-Centered Framework	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-29
K99MD018629	Racism-related stress and birth outcomes among Latinas: New tools for maximizing conceptual and methodological validity	UNIVERSITY OF CALIFORNIA BERKELEY	2025-04-29
K99MD018671	DELINEATING THE ROLE OF THE HOMOCYSTEINE-FOLATE-THYMIDYLATE SYNTHASE AXIS AND URACIL ACCUMULATION IN AFRICAN AMERICAN PROSTATE TUMORS	BAYLOR COLLEGE OF MEDICINE	2025-04-29
K99MD019292	A Multilevel Social Capital Approach to Address Cervical Cancer Screening and Follow Up Delays among Latinas in Safety-Net Settings	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-04-29
K99MD019294	Identifying unique biological factors as potential targets to mitigate colorectal cancer health disparities in Native Hawaiians	UNIVERSITY OF HAWAII AT MANOA	2025-04-29
R00MD015736	Neuroscientific Exploration of Cultural Protective Factors in American Indians	LAUREATE INSTITUTE FOR BRAIN RESEARCH	2025-04-29
R00MD015767	Synthesizing Trial and Real-world Data on the Use of Biologics in Patients with Severe Asthma	BRIGHAM AND WOMEN'S HOSPITAL	2025-04-29
R00MD016946	Identifying determinants of ADAR-dependency in triple-negative breast cancer	PURDUE UNIVERSITY	2025-04-29
R00MD016964	Comprehensive computational analysis of genetic and regulatory differences between individuals with African and European ancestries across four brain regions	NORTHWESTERN UNIVERSITY AT CHICAGO	2025-04-29
R00MH129983	Gene regulatory networks influencing neuron-microglia interactions in fetal brain development.	WASHINGTON UNIVERSITY	2025-04-29
R01AG079217-03S2	Targeting Microglial Lipoprotein Lipase in Alzheimer's disease	UNIVERSITY OF COLORADO DENVER	2025-04-29
R01AR069060-06S1	An Engineered Tidemark for Osteochondral Tissue Engineering	UNIVERSITY OF COLORADO	2025-04-29
R01AR078375-04S1	Engineering the Immune and Fibrotic Response in Volumetric Muscle Loss	UNIVERSITY OF OREGON	2025-04-29
R01AR079435-03S1	Skeletal Myosin-Binding Protein C Regulation and Structural Dynamics	UNIVERSITY OF ARIZONA	2025-04-29
R01AR079483-04S1	Neuroimmune Control of Scarless Skin Regeneration	UNIVERSITY OF PENNSYLVANIA	2025-04-29
R01AR081881-02S1	Longitudinal Biomechanics and Patient-Reported Outcomes after Periacetabular Osteotomy for Developmental Dysplasia of the Hip	WASHINGTON UNIVERSITY	2025-04-29
R01AR082652-02S1	Synthetic Cartilage-Capped, Regenerative Osteochondral Plugs to Heal Osteochondral Defects	TEXAS ENGINEERING EXPERIMENT STATION	2025-04-29
R01DK059418-25S1	Polycystins, cilia, and extracellular vesicles in C. elegans	RUTGERS, THE STATE UNIV OF N.J.	2025-04-29
R01DK069861-14S1	Restoring Central Regulation of Glucose Production in Type 2 Diabetes	ALBERT EINSTEIN COLLEGE OF MEDICINE	2025-04-29
R01DK107579-09S1	Preventing Diabetes in Latino Families	ARIZONA STATE UNIVERSITY-TEMPE CAMPUS	2025-04-29
R01DK112978-06S1	The Influence Of Gut Microbiota Stability In Inflammatory Bowel Disease	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2025-04-29
R01DK115507-07S1	Training Supplement in Enteric Virus Exploitation of Calcium Signaling	BAYLOR COLLEGE OF MEDICINE	2025-04-29
R01DK115655-05S1	Novel Role of Nephron Epithelialization in Nuclear Signaling	UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON	2025-04-29
R01DK122087-04S1	Optimizing a scalable intervention to maximize guideline-recommended diabetes testing after GDM	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-29
R01DK124327-04S1	Endothelin-1 in Obesity and Insulin Resistance	UNIVERSITY OF MISSISSIPPI MED CTR	2025-04-29
R01DK124427-04S1	Implementation Mapping to develop strategies for improving adoption, implementation and sustainment of CyberGEMS in hospital settings	SCRIPPS HEALTH	2025-04-29
R01DK127138-04S1	Chronic kidney disease of unknown etiology: applying a multidisciplinary approach to investigate the world's most common tubulointerstitial kidney disease	STANFORD UNIVERSITY	2025-04-29
R01DK128143-04S1	Estrogen-mediated immune regulation in human and experimental inflammatory bowel disease	CASE WESTERN RESERVE UNIVERSITY	2025-04-29
R01DK129340-03S1	Molecular Mechanisms Regulating Pancreatic Delta Cell Function and Dysfunction	VANDERBILT UNIVERSITY	2025-04-29
R01DK129552-04S1	Deciphering Epithelial Signals in the Liver to Drive Inflammation and Fibrosis	YALE UNIVERSITY	2025-04-29
R01DK130839-03S1	Mechanisms driving acute and chronic kidney function decline after immune checkpoint inhibitor therapy for cancer	MASSACHUSETTS GENERAL HOSPITAL	2025-04-29
R01DK131038-03S1	PPARgamma-regulated mechanisms in hepatocytes that promote NAFLD	UNIVERSITY OF ILLINOIS AT CHICAGO	2025-04-29
R01DK131214-03S1	Racial differences in MT1/MT2 receptor expression in human kidneys	RUTGERS BIOMEDICAL AND HEALTH SCIENCES	2025-04-29
R01DK131492-03S1	The Role of ERRa in liver lipid dysfunction and pathology	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-04-29
R01DK131533-03S1	Defining a Role for Liver Myeloid Cells in Viral Persistence under ART	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	2025-04-29
R01DK132873-02S1	Ex-vivo bioengineered technology to unravel dysfunction due to non-alcoholic steatohepatitis (NASH)	UNIVERSITY OF ARIZONA	2025-04-29

R01DK133301-03S1	The metabolic basis for impaired bile acid synthesis in malnutrition	BAYLOR COLLEGE OF MEDICINE	2025-04-29
R01DK133453-02S1	Leveraging early-life microbes to prevent type 1 diabetes	CHILDREN'S HOSP OF PHILADELPHIA	2025-04-29
R01DK133475-02S1	Development and validation of novel mouse models and expression vectors for characterizing severe alpha-thalassemia pathophysiology and evaluating gene therapy approaches.	CHILDREN'S HOSP OF PHILADELPHIA	2025-04-29
R01DK133645-03S1	Genome editing of human pancreatic islets to withstand ischemic injuries and promote immune evasion	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-29
R01DK134723-02S1	Role of PRKC alpha in Extracellular Matrix Remodeling	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-29
R01DK135099-02S1	Diversity Supplement for: Impact of a Healthy Checkout Policy on Healthfulness of Grocery Environments and Sales	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-29
R01DK135885-02S1	Diversity Supplement for Courtney Ortz: Older Adults Using Social Support to Improve Self-Care (OASIS): Adaption, Implementation, and Feasibility of Peer Support for Older Adults with T2DM in Appalach	UNIVERSITY OF KENTUCKY	2025-04-29
R01DK135949-02S1	Reducing Obesity Using Social Ties (ROBUST)	WEILL MEDICAL COLL OF CORNELL UNIV	2025-04-29
R01DK135999	KIBRA-induced biomechanical changes and therapeutic targeting in podocytes	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2025-04-29
R01DK136079-02S1	Hypothalamic lipid signaling in metabolism regulation	COLUMBIA UNIVERSITY HEALTH SCIENCES	2025-04-29
R01DK136240-02S1	Diversity Supplement to PARP1 and PARylation as novel effectors of gut inflammation	UNIVERSITY OF ARIZONA	2025-04-29
R01DK136795-02S1	A non-inferiority trial comparing synchronous and asynchronous remotely-delivered lifestyle interventions	UNIVERSITY OF CONNECTICUT STORRS	2025-04-29
R01DK138586-01S1	Alpha2/delta1- thrombospondin-3 signaling in the central control of metabolic function	TUFTS UNIVERSITY BOSTON	2025-04-29
R01DK139021-01S1	Sex Differences in Blood Pressure and Olfactory Receptor 558 (OLFR558)	JOHNS HOPKINS UNIVERSITY	2025-04-29
R01DK139109-01S1	3D real-time super-resolution cavitation mapping in laser lithotripsy of urinary stone disease	DUKE UNIVERSITY	2025-04-29
R01HD087417-08S1	Molecular basis of MED12 in the pathogenesis of uterine fibroids	UNIVERSITY OF TEXAS HLTH SCIENCE CENTER	2025-04-29
R01HD101578-04S1	Sleep, Brain Development, and Behavioral Correlates in a Longitudinal Cohort of Children at Risk for ASD	UNIVERSITY OF WASHINGTON	2025-04-29
R01HD106122-03S1	Influence of ADHD and Executive Functions on Developmental Dyslexia	MGH INSTITUTE OF HEALTH PROFESSIONS	2025-04-29
R01MD019279	Building Healthy Habits for Heart Health	UNIVERSITY OF CINCINNATI	2025-04-29
R01MD019281	Leveraging youth sports practices to increase physical activity among racial and ethnic minority mothers	BROWN UNIVERSITY	2025-04-29
R01MD019298	Transforming Care Delivery Models for at-Risk Young Adult Patients with Congenital Heart Disease and Amplifying Research Efforts to Improve Health Equity in Pediatric Chronic Disease Care	BAYLOR COLLEGE OF MEDICINE	2025-04-29
R01MH107506-08S1	A longitudinal study of brain development in children with autism	CHILDREN'S HOSP OF PHILADELPHIA	2025-04-29
R01MH107506-08S2	A longitudinal study of brain development in children with autism	CHILDREN'S HOSP OF PHILADELPHIA	2025-04-29
R01MH108665-09S1	Cell Type Specific Genomic and Functional Dissection of Fear-Off Amygdala Pathways	MCLEAN HOSPITAL	2025-04-29
R01MH121385-05S1	Neural mechanisms of risk and resilience in early childhood irritability	SAN DIEGO STATE UNIVERSITY	2025-04-29
R01MH122728-05S1	4/4: Improving the Part C Early Intervention Service Delivery System for Children with ASD: A Randomized Clinical Trial	UNIVERSITY OF MASSACHUSETTS BOSTON	2025-04-29
R01MH123544-05S1	Sex differences in CRH signaling in the ovBNST underlie effects of chronic stressors	RUTGERS, THE STATE UNIV OF N.J.	2025-04-29
R01MH124266-05S1	Biological Substrates of Maladaptive Stress Response in Early Childhood	WASHINGTON UNIVERSITY	2025-04-29
R01MH125158-05S1	Elevating Voices, Addressing Depression, Toxic Stress and Equity in Group Prenatal Care (EleVATE GC)	WASHINGTON UNIVERSITY	2025-04-29
R01MH126481-04S1	Foxp-regulated signaling pathways in brain development	UT SOUTHWESTERN MEDICAL CENTER	2025-04-29
R01MH126911-04S1	Integrated Reward-Circadian Rhythm Model of First Onset of Bipolar Spectrum Disorders in Adolescence	TEMPLE UNIV OF THE COMMONWEALTH	2025-04-29
R01MH126971-03S1	Representational dynamics for flexible learning in complex environments	BROWN UNIVERSITY	2025-04-29
R01MH129832-03S1	Neurobiologically-Based Subtyping of Multi-Cohort Samples with MDD and PTSD Symptoms	DUKE UNIVERSITY	2025-04-29
R03DK135896-02S1	Investigating the Cell Type- and Receptor-Specific Effects of Erythropoietin that Mediate Erythropoiesis and Thrombopoiesis in Primary Human Hematopoietic Progenitor Cells	UNIVERSITY OF CONNECTICUT SCH OF MED/DNT	2025-04-29
R21DK129893	Establishing the role of OCRL as a novel ciliary gene in weight regulation in human and murine models	COLUMBIA UNIVERSITY HEALTH SCIENCES	2025-04-29
R21DK133773	Fluorescence Lifetime Imaging (FLIm): a method to evaluate colon inflammation in vivo	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-04-29
R44AG082602	Innovative web-based service platform called Adult Wellbeing CheckUp (AWC) to assess older adults wellbeing, obtain evidence-based recommendations, and receive support to take action	BELLAGE, INC.	2025-04-29
U01DK130057-04S1	CKDu in Salvadoran and Nicaraguan Agricultural Communities	BOSTON UNIVERSITY MEDICAL CAMPUS	2025-04-29

F31AI183827	Delineating the impact of human karyopherins on hepatitis B virus species tropism	PRINCETON UNIVERSITY	2025-04-30
F31DC020664	Neural and Behavioral Indices of Balance Performance in Individuals with sensory loss	NEW YORK UNIVERSITY	2025-04-30
F31DC021377	Characterizing the Sensorimotor Transformation in Drosophila olfactory system	DREXEL UNIVERSITY	2025-04-30
F31DE032562	The Determinants of CD8 T cell Dysfunction in Oral Cavity Squamous Cell Carcinoma	WASHINGTON UNIVERSITY	2025-04-30
F31DK139749	Understanding diabetes and related-risk factors among adolescents of American Samoa	YALE UNIVERSITY	2025-04-30
F31DK142318	High-resolution functional mapping of non-coding sequences regulating fetal hemoglobin	HARVARD MEDICAL SCHOOL	2025-04-30
F31GM150215	The Role of Mammalian Diaphanous Formin 1 in Leading Edge Cell Protrusion	ALBERT EINSTEIN COLLEGE OF MEDICINE	2025-04-30
F31GM154424	Post-translational regulation of NORAD-induced Pumilio phase separation	UT SOUTHWESTERN MEDICAL CENTER	2025-04-30
K00MH134674	The role of dendritic excitability in controlling GABAergic synapse maturation	UNIVERSITY OF COLORADO DENVER	2025-04-30
K99ES035894	A Community Partnered Approach to Assessing the Impact of Prenatal Pesticide Exposure on Child Respiratory Outcomes in Mexico City	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2025-04-30
K99GM154063	Dual E3 ligase function of TRIM25 in modulating innate immunity	H. LEE MOFFITT CANCER CTR & RES INST	2025-04-30
P01CA257904-03S1	Translational Studies in FLASH Particle Radiotherapy	UNIVERSITY OF PENNSYLVANIA	2025-04-30
P50HD112034-02S1	Immunological, epigenetic and developmental determinants of early pregnancy success	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-04-30
R00AG070102-04S1	Development of a Predictive Frailty Clock & Longitudinal Investigation of its Epigenetic Determinants	INSTITUTE FOR SYSTEMS BIOLOGY	2025-04-30
R00AG075259	Pathways Linking Negative Self-Views of Aging to Physical Activity in Daily Life: An Intensive Within-Person Approach	UNIVERSITY OF MISSISSIPPI	2025-04-30
R00MH126430	mRNA Alternative Splicing Regulatory Networks in the Specification of Cortical Interneuron Subtypes	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-30
R01AG072658-03S2	Characterizing and modulating neurocognitive processes of learning to trust and distrust in aging	UNIVERSITY OF FLORIDA	2025-04-30
R01AI185750	Enhancing T and B cell responses to Plasmodium infection and vaccination via IL-15	HENNEPIN HEALTHCARE RESEARCH INSTITUTE	2025-04-30
R01AI186275-01S1	PD-L1 reverse signaling in liver homeostasis and disease	UNIVERSITY OF COLORADO DENVER	2025-04-30
R01CA251676-05S1	Administrative Supplement to Dual function of HSP70 in cytoprotection of tumor cells and generation of permissive microenvironment	WAYNE STATE UNIVERSITY	2025-04-30
R01CA270788-03S1	Defining the Roles of BRCA2 and RAD51 in PARPi Response	YALE UNIVERSITY	2025-04-30
R01CA274743-03S1	Mechanisms of cell proliferation in whole-genome doubled cells	BOSTON UNIVERSITY MEDICAL CAMPUS	2025-04-30
R01DA059293	The role of neuronal ensemble Rac1 activity in cocaine seeking behavior	UNIVERSITY OF FLORIDA	2025-04-30
R01DA060784	Teaching Youth & Families Self-Regulation Skills to Disrupt the Impact of Adverse Childhood Experiences: Preventing Substance Use in Adversity-Impacted Youth	UNIVERSITY OF CALIFORNIA-IRVINE	2025-04-30
R01DA060796	Virtual Reality Treatment for Chronic Pain and OUD In Opioid Treatment Programs: A Randomized Controlled Trial	ALBERT EINSTEIN COLLEGE OF MEDICINE	2025-04-30
R01DC021070	Identification and characterization of novel functions for the Usher proteins in the inner ear	CREIGHTON UNIVERSITY	2025-04-30
R01DC021839	Family language planning and language acquisition among deaf and hard of hearing children	UNIVERSITY OF ROCHESTER	2025-04-30
R01DK131236-03S1	Molecular control of mechanical forces driving buckling morphogenesis of the small intestine	COLUMBIA UNIV NEW YORK MORNINGSIDE	2025-04-30
R01DK132953	The Impact of Structural Racism on Racial/Ethnic Disparities in End-Stage Kidney Disease from Healthy Population to Mortality	PENNSYLVANIA STATE UNIVERSITY, THE	2025-04-30
R01DK132953-03S1	The Impact of Structural Racism on Racial/Ethnic Disparities in End-Stage Kidney Disease from Healthy Population to Mortality	PENNSYLVANIA STATE UNIVERSITY, THE	2025-04-30
R01DK135838	The Role of Structural Racism on Disparities in Clinical Outcomes for Diabetes: A Mixed Methods Study	MEDICAL COLLEGE OF WISCONSIN	2025-04-30
R01EB035231	Deep learning for opportunistic screening for osteoporosis and osteopenia from radiographs	MAYO CLINIC JACKSONVILLE	2025-04-30
R01ES034303	Research Employing Environmental Systems and Occupational Health Policy Analyses to Interrupt the Impact of Structural Racism on Agricultural Workers and Their Respiratory Health (RESPIRAR)	UNIV OF MARYLAND, COLLEGE PARK	2025-04-30
R01ES035740	Illuminating the role of historical structural racism in the neighborhood exposome and modern-day child mental health	HENRY FORD HEALTH + MICHIGAN STATE UNIVERSITY HEALTH SCIENCES	2025-04-30
R01EY033477-03S1	Sustained release of fenofibrate for the treatment of diabetic retinopathy	VIRGINIA COMMONWEALTH UNIVERSITY	2025-04-30
R01EY033816-01A1S1	Compartmentalized cAMP signaling in reactive astrocytes	STANFORD UNIVERSITY	2025-04-30
R01EY035994	Leveraging Artificial Intelligence to Prevent Vision Loss from Diabetes Among Socioeconomically Disadvantaged Communities	UNIVERSITY OF WISCONSIN-MADISON	2025-04-30
R01HD103700-04S1	Brain Injury Outpatient Education and Care Navigation	SEATTLE CHILDREN'S HOSPITAL	2025-04-30

R01HD107083-03S1	Identifying Optimal Antibiotic Regimens to Treat Urinary Tract Infections During Pregnancy	WASHINGTON UNIVERSITY	2025-04-30
R01MD016389	Long-Term Effects of COVID-19-induced Health Care Delivery Changes on Patient & Workforce Processes & Outcomes in Safety Net Practices Caring for Health Disparity Populations	CASE WESTERN RESERVE UNIVERSITY	2025-04-30
R01MD018928	Longitudinal Evaluation of Research Career Intentions among Students Underrepresented in Medicine	YALE UNIVERSITY	2025-04-30
R01MD019525	ADEPT: Assessing Diversity Effects Post Affirmative Action Restrictions in Medical Schools	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	2025-04-30
R01MD019814	The Development, Implementation, and Evaluation of a Social Engagement Support System	UNIVERSITY OF MARYLAND BALTIMORE COUNTY	2025-04-30
R01MH125430-04S1	MULTIREGIONAL ELECTRICAL ENCODING OF SOCIAL AGGRESSION	DUKE UNIVERSITY	2025-04-30
R01MH125430-04S2	MULTIREGIONAL ELECTRICAL ENCODING OF SOCIAL AGGRESSION	DUKE UNIVERSITY	2025-04-30
R03EB035177-01S1	Magnetic resonance imaging methods to track Treg distribution and homing for clinical applications	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-30
R21DK133754	TWEAK-Fn14 regulation of non-canonical NF-kB signaling in chronic renal inflammation	QUEEN'S MEDICAL CENTER	2025-04-30
R21DK134815	Transforming motivational interviewing into a computable model for automated patient diabetic counseling.	UNIVERSITY OF TEXAS MED BR GALVESTON	2025-04-30
R21DK134906	Comfort eating in the Eating in America Study: New insights to inform prevention and intervention efforts across the lifespan	NATIONAL OPINION RESEARCH CENTER	2025-04-30
R21DK134931	Integrating Computational and Experimental Models to Predict Toxicity of the Pancreas	SAN DIEGO STATE UNIVERSITY	2025-04-30
R21DK135965	Joint Patient and Caregiver Intervention for Older African Americans with Poorly Controlled Type 2 Diabetes (Joint Home-DM-BAT)	MEDICAL COLLEGE OF WISCONSIN	2025-04-30
R21DK136122	Role of Kidney Microvasculature-Secreted Factors in Neuropilin Signaling in Proximal Tubule During Diabetic Kidney Disease	WAYNE STATE UNIVERSITY	2025-04-30
R21DK137123	The inward rectifier potassium channel Kir7.1 is at the center of energy homeostasis regulation	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-04-30
R21DK137191	Evaluating Microaggressions among Latinx Individuals with Obesity	UNIVERSITY OF HOUSTON	2025-04-30
R21DK138178	Small molecules targeting obesity-linked diabetes	GEORGIA STATE UNIVERSITY	2025-04-30
R21DK138390	Catheter-associated molecular patterns and arteriovenous fistula failure	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	2025-04-30
R21DK138393	Novel mechanism of activation of the Renin-Angiotensin-System by inflammatory cells in diabetic kidney disease	WAYNE STATE UNIVERSITY	2025-04-30
R21DK138411	Energizing good fat by neurovascular development	UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON	2025-04-30
R21DK138414	Liquid biopsy technology towards individualized immunosuppression therapy	UNIVERSITY OF FLORIDA	2025-04-30
R21DK139507	Implications of gastrointestinal motility and diet on irritable bowel syndrome associated symptoms	CHILDREN'S HOSP OF PHILADELPHIA	2025-04-30
R21DK139557	Development of a Culturally Adapted Digital Health Application for Older Hispanics with Type 2 Diabetes	UNIVERSITY OF GEORGIA	2025-04-30
R25AG069719	Get Experience in Aging Research Undergraduate Program (GEAR UP)	UNIVERSITY OF PENNSYLVANIA	2025-04-30
R25AG071461	Advancing Native American Diversity in Aging Research through Undergraduate Education (Native American ADAR)	MAGEE-WOMEN'S RES INST AND FOUNDATION	2025-04-30
R25AG076387	ACOA/MSTEM THRIVE Program for Undergraduates	UNIVERSITY OF ARIZONA	2025-04-30
R25AG090804	UMB RAMP: UMB Research And Mentoring Program to develop skills and promote interest in STEM fields through hands-on exposure to academic research among West Baltimore Youth	UNIVERSITY OF MARYLAND BALTIMORE	2025-04-30
R25DK113659	UCLA Short-Term Research Experience to Unlock Potential (UCLA STEP-UP)	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-04-30
R25DK136141	Dialysis Access Justice, Equity, Diversity, Inclusion (DA-JEDI) Program.	AMERICAN SOCIETY OF NEPHROLOGY, INC.	2025-04-30
R25GM121231	Northwestern University Postbaccalaureate Research Education Program	NORTHWESTERN UNIVERSITY AT CHICAGO	2025-04-30
R25GM137382	Xavier University of Louisiana-Mobile Outreach for Laboratory Enrichment (XULA-MOLE)	XAVIER UNIVERSITY OF LOUISIANA	2025-04-30
R25GM142060	Iterative Design to Engage All (IDEA) Learners: A teacher-scientist collaboration to feature biomedical research and engage diverse high school students	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-04-30
R25GM154345	Opening WINDOWS for high school learners to see and explore dentistry and dental research careers	OREGON HEALTH & SCIENCE UNIVERSITY	2025-04-30
R25GM154351	Using place-based education to engage Bronx high schoolers and teachers in health disparity research	HERBERT H. LEHMAN COLLEGE	2025-04-30
R25MD019151	CBESS: a pipeline program to increase linguistic and geographic diversity in STEM + health	UNIVERSITY OF NEVADA RENO	2025-04-30
R35GM140846-04S1	Mechanisms of modulation of transmembrane interactions	UNIVERSITY OF TENNESSEE KNOXVILLE	2025-04-30
R35GM141927-04S1	Protection Against Nosocomial Infections After Severe Burn Injury Through Trained Immunity	VANDERBILT UNIVERSITY MEDICAL CENTER	2025-04-30
R35GM146795-03S1	Genetic Mechanisms of Tissue-Resident Macrophage Maintenance and Function (Supplement)	MICHIGAN STATE UNIVERSITY	2025-04-30

R36MH134774	The Effects of Structural Inequities and Syndemics on Willingness to Participate in HIV Research among Black Women	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-04-30
RF1MH130371-01S1	BRAIN Integrated Resource for Human Anatomy and Intracranial Neurophysiology	UT SOUTHWESTERN MEDICAL CENTER	2025-04-30
RF1MH130371-01S2	BRAIN Integrated Resource for Human Anatomy and Intracranial Neurophysiology	UT SOUTHWESTERN MEDICAL CENTER	2025-04-30
T32AG023480	Harvard Translational Research in Aging Training Program	HEBREW REHABILITATION CENTER FOR AGED	2025-04-30
T32GM136499	G-RISE at The City College of New York	CITY COLLEGE OF NEW YORK	2025-04-30
T32GM136501	G-RISE at the University of North Texas	UNIVERSITY OF NORTH TEXAS	2025-04-30
T32GM140911	G-RISE at Old Dominion University	OLD DOMINION UNIVERSITY	2025-04-30
T32GM141739	G-RISE at Auburn University	AUBURN UNIVERSITY AT AUBURN	2025-04-30
T32GM141862	G-RISE at UC Merced	UNIVERSITY OF CALIFORNIA, MERCED	2025-04-30
T32GM144873	Training in Molecular and translational Cell Dynamics	UNIVERSITY OF TOLEDO HEALTH SCI CAMPUS	2025-04-30
T32GM144876	G-RISE at UMBC	UNIVERSITY OF MARYLAND BALTIMORE COUNTY	2025-04-30
T32GM144895	G-RISE at Delaware State University: Diversifying neuroscience through predoctoral training at an HBCU	DELAWARE STATE UNIVERSITY	2025-04-30
T32GM144896	G-RISE at Ponce Health Sciences University	PONCE SCHOOL OF MEDICINE	2025-04-30
T32GM144919	G-RISE at the University of Texas at El Paso	UNIVERSITY OF TEXAS EL PASO	2025-04-30
T32GM144927	G-RISE at Meharry Medical College	MEHARRY MEDICAL COLLEGE	2025-04-30
T32GM148395	CAU G-RISE	CLARK ATLANTA UNIVERSITY	2025-04-30
T32GM152384	G-RISE at the University of Puerto Rico Rio Piedras	UNIVERSITY OF PUERTO RICO RIO PIEDRAS	2025-04-30
T32GM152760	G-RISE: Educating and Training Tomorrow's Biomedical Workforce	MOREHOUSE SCHOOL OF MEDICINE	2025-04-30
T32HD007014-48S1	Diversity supplement	UNIVERSITY OF WISCONSIN-MADISON	2025-04-30
U19AI089992-13S1	Immune signatures of vaccine responses in vulnerable populations	YALE UNIVERSITY	2025-04-30
F31HD112158	Molecular mechanisms of sex-specific differentiation	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2025-05-01
F31HD112191	ATR signaling activation by the 9-1-1 complexes during mammalian meiosis	CORNELL UNIVERSITY	2025-05-01
F31HD113328	Mapping the cellular impacts of Chd8 haploinsufficiency and characterizing microglial activity in Chd8 mutant mice	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-05-01
R01HD105676-03S1	Prevention of Attachment Insecurity, Physiological Dysregulation, and Child Behavior Problems	UNIV OF MARYLAND, COLLEGE PARK	2025-05-01
R01HD109158-02S1	Sources of on information on pregnancy health and infant care among Latino immigrant parents	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-05-01
R01HD110860-02S1	Gravida traumatic brain injury (TBI) impacts neurodevelopment of the offspring	UNIVERSITY OF ARIZONA	2025-05-01
R01HD110860-02S2	Gravida traumatic brain injury (TBI) impacts neurodevelopment of the offspring	UNIVERSITY OF ARIZONA	2025-05-01
UC2HD113039-02S1	Diversity Supplement to Integrated Transporter Elucidation Center	RUTGERS BIOMEDICAL AND HEALTH SCIENCES	2025-05-01
K99AI180649	Regulatory T cell coordination of the mucosal NK cell response during viral infection	FRED HUTCHINSON CANCER CENTER	2025-05-02
K99AI182451	Molecular understanding of maternal humoral responses to pregnancy	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-05-02
R00AI166094	Stress-induced transposon mobilization in the human fungal pathogen Cryptococcus	DUKE UNIVERSITY	2025-05-02
R01AG037514-13S1	Role of Mitochondrial Homeostasis in Animal Aging	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-05-02
R01AG061785-04S1	Circadian changes in network excitability and Alzheimer disease pathogenesis	UNIVERSITY OF ALABAMA AT BIRMINGHAM	2025-05-02
R01AG072587-02S1	Structural and Biological Characterization of Diverse Oligomers Derived from Abeta	UNIVERSITY OF CALIFORNIA-IRVINE	2025-05-02
R01AG074570-04S1	Chemical approaches to selectively target beta-rich amyloidosis	UNIVERSITY OF NOTRE DAME	2025-05-02
R01AG074709-02S1	Diversity Supplement toTraffic-related air pollution exacerbates AD-relevant phenotypes in a genetically susceptible rat model via neuroinflammatory mechanism(s)	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-05-02
R01AG075654-03S1	Effects of Advanced Glycation Endproducts on Type 2 Diabetic and Fragility Fractures	RENSSELAER POLYTECHNIC INSTITUTE	2025-05-02
R01AG075900-03S1	Contributions of tau-mediated translational dysregulation to pathogenesis and progression of fronto-temporal dementia	UNIVERSITY OF FLORIDA	2025-05-02
R01AG076075-03S1	Regulation of macrophage metabolism in aged muscle during recovery	UNIVERSITY OF UTAH	2025-05-02
R01AG076956-03S1	Neural stem cell rejuvenation through single cell pharmacogenomics	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-05-02
R01AG077579-03S2	Understanding Biological and Lifestyle Contributions to Alzheimer's Disease Pathology and Clinical Profiles in Black Women: Defining Prevention Targets in High Risk Groups	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-05-02
R01AG078609-02S1	ASK1 inhibition as a novel strategy to regulate immune function and promote regeneration	THOMAS JEFFERSON UNIVERSITY	2025-05-02

R01AG079193-02S1	Endoscopy for nasal amyloid deposits, Administrative Supplement under Virus and olfactory system interactions accelerate Alzheimer's disease pathology	UNIVERSITY OF COLORADO DENVER	2025-05-02
R01AG079193-02S2	Postbaccalaureate studies by Ms. Amalia Bustillos understanding whether viral infection of the olfactory system accelerate Alzheimer's disease	UNIVERSITY OF COLORADO DENVER	2025-05-02
R01AG079907-02S1	Proactive pharyngeal swallowing exercises: Building muscular reserve in pre-frail older adults	NEW YORK UNIVERSITY	2025-05-02
R01AG080037-02S1	Diversity Supplement: The role of lymph node structural organization in naive T cell decline with age	MAYO CLINIC ARIZONA	2025-05-02
R01AG080470-02S1	Bilingual Factors Associated with Cognitive Reserve and Linguistic Resilience in Hispanics with Primary Progressive Aphasia	UNIVERSITY OF TEXAS AT AUSTIN	2025-05-02
R01AG080829-02S1	Earlier-Life Predictors of Midlife Risk Factors for Dementia: A 35-Year Follow-up Wallace Admin Suppl	JOHNS HOPKINS UNIVERSITY	2025-05-02
R01AG081421-02S1	Assessing the role of APOE in glial lipid droplet metabolism and function	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-05-02
R25DA050735	The Substance Misuse and Addiction Research Traineeship (SMART)	UNIVERSITY OF SOUTH FLORIDA	2025-05-02
R25DA051338	EDUCATE (Educating Diverse Undergraduates for Careers in Addiction/Substance Abuse Research via Training Experiences) Scholars Program at UMBC	UNIVERSITY OF MARYLAND BALTIMORE COUNTY	2025-05-02
R25DA051339	Building Undergraduate Research Training as a Foundation for Diversifying Addiction Research	VIRGINIA COMMONWEALTH UNIVERSITY	2025-05-02
R25DA051342	Growing the Genetics of Addiction Workforce with URM Faculty-Student Research Experiences	JACKSON LABORATORY	2025-05-02
R25DA055280	Strengthening Pathways between Hispanic-Serving Institutions and Leadership in Addiction Science	NEW YORK UNIVERSITY SCHOOL OF MEDICINE	2025-05-02
R25DA056016	Rising STARS (Scientific Training in Alcohol Research and other Substances) Program	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-05-02
R25DA056910	Increasing Minority Physician and APRN Clinician-scientist Research Training To Equalize Addiction Medicine (IMPACT TEAM)	MICHIGAN STATE UNIVERSITY	2025-05-02
R25DA058482	CUBE: A Collaborative Undergraduate Biostatistics Experience to Diversify and Bring Awareness to the Field of Collaborative Biostatistics	VIRGINIA POLYTECHNIC INST AND ST UNIV	2025-05-02
R25DA059883	NCCU Duke - Substance Use Research & Education (ND-SURE)	NORTH CAROLINA CENTRAL UNIVERSITY	2025-05-02
R25DA061485	Training in Research Undergraduate Experience through the Rutgers Addiction Research Center: The TRUE RARC Scholar Program	RUTGERS BIOMEDICAL AND HEALTH SCIENCES	2025-05-02
R25DA061492	Preparing Indigenous Scientists to Lead Innovative Substance Use Research: The Native Children's Research Exchange Scholars Program	UNIVERSITY OF COLORADO DENVER	2025-05-02
R25DA061948	Utilizing Community Partnerships to enhance Indigenous STEM Education for American Indian Youth	CALIFORNIA STATE UNIVERSITY SAN MARCOS	2025-05-02
RF1AG083753-01S1	Role of APOE in endosomal processing of alpha-synuclein	WASHINGTON UNIVERSITY	2025-05-02
U01AG077925-04S1	Assessing the Interplay Between Inflammatory Signaling and Epigenetic Dysregulation in Age-associated Clonal Hematopoiesis and Leukemia Initiation	JACKSON LABORATORY	2025-05-02
K01DE033698	Real-world Evidence Study with Patient Input to evaluate Treatment Effects in Trigeminal Neuralgia (RESPITE-TN)	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-05-05
K01MD015768	Mental health phenotypes shaped by trauma exposure, symptom severity, and individual characteristics among recent Latinx immigrant adults	UNIVERSITY OF COLORADO DENVER	2025-05-05
K01MD019325	Enlace Familiar: Combating Mental Health Stigma, Improving Mental Health Literacy, Supporting Mental Health Discussions at Home, and Access to care among Latinx Adolescents from Mixed Status Families	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-05-05
R01ES036236	Disentangling the role of culture, life stage, and information design to facilitate equity in data report back	UNIVERSITY OF ARIZONA	2025-05-05
R01MD018459	Elucidating the high and heterogeneous risk of gestational diabetes among Asian Americans: an integrative approach of metabolomics, lifestyles, and social determinants	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-05-05
R38HL172263	The Columbia University Irving Medical Center (CUIMC) NHLBI Health Equity StARR Program	COLUMBIA UNIVERSITY HEALTH SCIENCES	2025-05-05
R44MD017106	Reducing Hypertension among African American Men: A Mobile Stress Management Intervention to Address Health Disparities	ISA ASSOCIATES, INC.	2025-05-05
F31GM146427	Function of GATA3-PARP1 complex in breast cancer during GATA3-mediated cellular reprogramming	UNIVERSITY OF NORTH DAKOTA	2025-05-06
F31GM147952	Investigating the conformational changes of the portal protein that drive DNA packaging in a dsDNA virus	UNIVERSITY OF CONNECTICUT STORRS	2025-05-06
R01AR075813-04S1	Impact of Loss-of-function NADPH Oxidase Variants on B-Cell Activation in SLE	SEATTLE CHILDREN'S HOSPITAL	2025-05-07
F31NR021235	Examining Health Disparities in the use of Hematopoietic Cell Transplants for HIV-related Lymphoma	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-05-08
K00DA057923	Investigation of how sex steroids and nicotinic acetylcholine receptors promote cocaine self-administration	UNIVERSITY OF CALIFORNIA, SAN DIEGO	2025-05-09

R01AG083464	Identifying salient factors that influence physician practices in mitigating patient misinformation	WAKE FOREST UNIVERSITY HEALTH SCIENCES	2025-05-09
R01MD016867	Community-Centered Interventions for Improved Vaccine Uptake for COVID (CIVIC)	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-05-09
R01MD018727	Understanding Mis- and Disinformation About Health Care Access and Their Impacts on Decision-Making Among Latino Immigrants	UNIVERSITY OF HAWAII AT MANOA	2025-05-09
R21AI185162	Building a Harmonized Village Network Data Resource for Realistic Disease Transmission Models	DUKE UNIVERSITY	2025-05-09
F31AI176822	MicroRNA-31 regulates neutrophil migration and activation	PURDUE UNIVERSITY	2025-05-12
R21DA056725	Auditing Social Media Algorithmic Pathways to Measure Prevalence of Online Misinformation Related to Opioid Misuse	UNIVERSITY OF WASHINGTON	2025-05-12
R01AG044346	Mechanisms Specific to the Beneficial Effects of Dietary Restriction	HARVARD SCHOOL OF PUBLIC HEALTH	2025-05-13
R01DK136632	Histone chaperones and cell state regulation	UNIVERSITY OF CINCINNATI	2025-05-14
F31DA059253	Innovations in Modeling Existing and Emerging Policies to Improve Warning Systems for Opioid Overdoses	YALE UNIVERSITY	2025-05-15
F31DA061593	Community and big-data system approaches to identifying and understanding the health impact of xylazine	BROWN UNIVERSITY	2025-05-15
F31GM146347	Epigenetic and transcriptional consequences of Intellectual Disability-associated mutations in the histone lysine demethylase KDM5.	ALBERT EINSTEIN COLLEGE OF MEDICINE	2025-05-15
R01MH121245-05S1	Evaluating the HITSystem to Improve PMTCT Retention and Maternal Viral Suppression in Kenya	UNIVERSITY OF KANSAS MEDICAL CENTER	2025-05-15
R25HD108670	Bioengineering Research and Interdisciplinary Training – ESTEEMED (BRITE)	KENNESAW STATE UNIVERSITY	2025-05-15
UM1TR004360-02S2	Wright Regional Center for Clinical and Translational Science	VIRGINIA COMMONWEALTH UNIVERSITY	2025-05-15
UM1TR004360-02S1	Wright Regional Center for Clinical and Translational Science	VIRGINIA COMMONWEALTH UNIVERSITY	2025-05-16
F31GM149178	F31 Microtubule function in the onset of whole-body regeneration	NORTHWESTERN UNIVERSITY	2025-05-19
F31GM150276	Contribution of cell mechanics in promoting collective behavior for supracellular migration	NEW YORK UNIVERSITY	2025-05-19
K99ES036277	Phthalate Mixtures and the Interconnection of Child Neurobehavior and Obesity	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	2025-05-19
R25AI187726	AR Tech-DaSH: Arkansas Technology and Data Science in Health and Medicine	UNIV OF ARKANSAS FOR MED SCIS	2025-05-19
R00ES031050-04S1	A systematic study of the environmental etiology of autism spectrum disorder using high-throughput behavioral screening	UNIVERSITY OF WASHINGTON	2025-05-20
R01NR020439	Structural Racism and Engagement of Family Caregivers in Serious Illness Care	UNIV OF MASSACHUSETTS MED SCH WORCESTER	2025-05-21
R01DC021835	Processing and localization of the mechanotransduction channel subunit TMC1	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-05-22
R01HD115985	The California Abundant Birth Project Evaluation: Advancing Birth Equity through Guaranteed Income for Pregnant People	UNIVERSITY OF CALIFORNIA BERKELEY	2025-05-22
R01DA059310	Microglial modulation of neurocircuits in HIV/cocaine comorbidity	UNIVERSITY OF SOUTH CAROLINA AT COLUMBIA	2025-05-23
R01DC021067	The significance of nominally non-responsive neural dynamics in auditory perception and behavior	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-05-23
R01DC021325	ACTIVITY-DRIVEN PLASTICITY OF THE HAIR CELL CYTOSKELETON	UNIVERSITY OF KENTUCKY	2025-05-23
R01MD017051	Digital health platform (DHP) to deliver Mindfulness as a Stress Management Intervention Leveraging Electronic (SMILE) health records for racial and ethnic populations during the COVID-19 pandemic	UNIV OF NORTH CAROLINA CHAPEL HILL	2025-05-23
R25AG076406	UW-Milwaukee Promoting Equity, Diversity, and Academic Success Through Aging Research Program (UWM STAR)	UNIVERSITY OF WISCONSIN MILWAUKEE	2025-05-26
F31DA059262	Exploration of the unique neurobehavioral profile of sequential opioid-stimulant polysubstance use disorders	UNIVERSITY OF WASHINGTON	2025-05-27
F31AG081095	Investigating neuropeptide signals that slow cognitive aging in C. elegans	BAYLOR COLLEGE OF MEDICINE	2025-05-28
R25GM142044	Frugal Science Academy: Training K-12 innovators and democratizing synthetic biology tools	GEORGIA INSTITUTE OF TECHNOLOGY	2025-05-28
R25GM142087	Engineering Solutions for Better Health: Genetic Technology and Biomedical Engineering for Secondary Classrooms	UNIVERSITY OF UTAH	2025-05-28
R25GM146290	STEAM Education and Training for Underrepresented Students and Teachers in the Arkansas Delta	UNIVERSITY OF ARKANSAS AT FAYETTEVILLE	2025-05-28
R25GM154354	Empowering Rural Students to Address Public and Climate Health Through Research	UNIVERSITY OF MONTANA	2025-05-28
R25GM154358	Reducing Inequities by Promoting Participatory Learning Experiences in Science (RIPPLES)	FRED HUTCHINSON CANCER CENTER	2025-05-28
R25MD017950	Clinical Research Scholars Training (CREST) Program	SUNY DOWNSTATE MEDICAL CENTER	2025-05-28
R01HD104801-05S1	Prenatal Social Connection and Disruption During the COVID-19 Pandemic: Effects on Maternal and Infant Health	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-05-30
R01HD108198-05S1	Disruption of semen liquefaction using specific KLK3 inhibitors as a new contraceptive	UNIVERSITY OF MISSOURI-COLUMBIA	2025-05-30

R01HD108236-04S1	Effectiveness and acceptability of two insertable device models for non-surgical management of obstetric fistula in Ghana: a randomized crossover trial	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-05-30
F31AG079597	Astrocyte-specific in vivo molecular signatures of APOE genetic risk in Alzheimer's disease	EMORY UNIVERSITY	2025-05-31
F31AG082498	Modeling Alzheimer's Disease in Hispanic Latino populations using human cortical organoids	UNIVERSITY OF TEXAS SAN ANTONIO	2025-05-31
F31AG086042	The Role of Peripheral Aged CD8+ T Cells in Hippocampal-Dependent Cognitive Decline	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-05-31
F31DA053795	Prenatal Opioid Exposure and Inflammation: The Role of the Microbiome and Epigenome.	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	2025-05-31
F31DA060615	The role of dopamine in OFC-DMS plasticity in punishment-resistant reward-seeking behavior	NORTHWESTERN UNIVERSITY AT CHICAGO	2025-05-31
F31DA060690	Evaluation of a Pharmacist-Integrated Model of Opioid Use Disorder Treatment to Increase Naloxone Co-Prescribing in Primary Care	DARTMOUTH COLLEGE	2025-05-31
F31DC021111	Vocabulary Encoding and Retention in Autism via Social Cognition (VERAS)	NORTHEASTERN UNIVERSITY	2025-05-31
F31DC021859	Mitochondrial dysfunction as a promoter of stria vascularis degeneration and inflammation in metabolic presbyacusis	MEDICAL UNIVERSITY OF SOUTH CAROLINA	2025-05-31
F31EY035931	Uncovering the role of Ankyrins in photoreceptor wiring	BAYLOR COLLEGE OF MEDICINE	2025-05-31
F31EY036722	Interaction of Genetic and Environmental Factors in Keratoconus	AUGUSTA UNIVERSITY	2025-05-31
F31EY036742	Transcriptional and Developmental Basis of the Human X-linked Homeotic Hotspot	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-05-31
F31EY037171	Evaluation of Human Retinal Ganglion Cell Regenerative Potential	JOHNS HOPKINS UNIVERSITY	2025-05-31
F31EY037180	Integrate neuroimaging, molecular quantitation, and cytoarchitecture to elucidate the development of myelination in human visual cortex.	STANFORD UNIVERSITY	2025-05-31
F31EY037190	The development and connectivity of starburst amacrine cells in human retinal organoids	JOHNS HOPKINS UNIVERSITY	2025-05-31
F31GM151830	Investigating the Role of HSPE1 in Regulating OPA1	JOHNS HOPKINS UNIVERSITY	2025-05-31
F31GM154483	Mechanism of translation initiation through the non-canonical initiation factor eIF2A	UNIVERSITY OF UTAH	2025-05-31
F31MH134470	Identifying Risk Mechanisms Underpinning the Association Between Callous-Unemotional Traits and Externalizing Behavior	UNIVERSITY OF ROCHESTER	2025-05-31
F31MH134582	Anterior Cingulate Cortex preferentially drives dorsal CA1 deep neuronal activity during sharp-wave ripples for memory consolidation	DREXEL UNIVERSITY	2025-05-31
K00MH134248	NE contributions to Lateral habenula control of action evaluation under chronic stress	BOSTON UNIVERSITY MEDICAL CAMPUS	2025-05-31
K99AG086530	Alzheimer's Disease and Related Dementia Neuropathologies and Exposures to Traffic Pollution Mixtures	UNIVERSITY OF WASHINGTON	2025-05-31
K99EY034928	Retina-derived extracellular vesicles in diabetic retinopathy: their potential role in pathogenesis and therapy	UNIVERSITY OF CALIFORNIA-IRVINE	2025-05-31
K99EY035758	Understanding how mitochondrial interaction with other organelles in the retinal pigment epithelium (RPE) affect its function in the outer retina	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-05-31
K99EY036650	Delineating the neural computational network for object recognition	WASHINGTON UNIVERSITY	2025-05-31
R00AG076966	Improving Access to Alzheimer's disease and Related Dementias care services for Latinx individuals at Community Health Clinics. A multiphase mixed methods study.	UNIVERSITY OF WISCONSIN-MADISON	2025-05-31
R01AR072304-07S1	Therapeutic strategies for treatment of giant congenital melanocytic nevi	MASSACHUSETTS GENERAL HOSPITAL	2025-05-31
R01AR078811-03S1	Clinically Assessed Risk Factors for a Second ACL Injury Using an Innovative Wearable Sensor – Diversity Supplement	VIRGINIA POLYTECHNIC INST AND ST UNIV	2025-05-31
R01DA060795	Impact of the New York State Medicaid Value-Based Payment Model on Opioid Use Treatment and Equity	CAMBRIDGE HEALTH ALLIANCE	2025-05-31
R01DC008524-18S1	AphasiaBank: A Shared Database for the Study of Aphasic Communication	CARNEGIE-MELLON UNIVERSITY	2025-05-31
R01DC020402-03S1	Addressing Structural Disparities for Children with Early Communication Disorders (ASCEND)	OREGON HEALTH & SCIENCE UNIVERSITY	2025-05-31
R01DC020459-03S1	Extratelencephalic contributions to auditory categorization	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-05-31
R01DC021326	Molecular Imaging for diagnosis and monitoring of Otitis Media	STANFORD UNIVERSITY	2025-05-31
R01EY026662-09S1	Metabolic Vulnerability as a Diseased Target for Glaucoma	UNIVERSITY OF NORTH TEXAS HLTH SCI CTR	2025-05-31
R01EY031972-05S1	Activity-Dependent Mechanisms of Memory Consolidation	STANFORD UNIVERSITY	2025-05-31
R01EY034110-02S1	Postnatal Mice as a Pediatric Research Model for Investigating Direct Ocular Exposure to Vesicants	UNIVERSITY OF ALABAMA AT BIRMINGHAM	2025-05-31
R01EY034626-02S1	Cortical and Brainstem Contributions to Binocular Eye Movements	SMITH-KETTLEWELL EYE RESEARCH INSTITUTE	2025-05-31
R01EY035028-02S1	Retinal mechanisms underlying the optokinetic reflex	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-05-31
R01EY035254-03S1	Microglial plasticity mechanisms in the developing retina	BAYLOR COLLEGE OF MEDICINE	2025-05-31
R01HD106862-04S1	Stepped care to optimize PrEP effectiveness in pregnant and postpartum women (SCOPE-PP) in South Africa	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-05-31

R01HD114645-01S1	The roles of mouse Y chromosome Zfy genes in male reproduction.	UNIVERSITY OF HAWAII AT MANOA	2025-05-31
R01MD019042	ACCTiVATE: Achieving Chronic Care equiTy by leVeraging the Telehealth Ecosystem	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-05-31
R21EY032740-02S1	Treatment strategies for ocular toxicity from chloropicrin	MICHIGAN STATE UNIVERSITY	2025-05-31
R25AG043365	Frontiers in Alzheimer's and Aging Research Experiences	MAGEE-WOMEN'S RES INST AND FOUNDATION	2025-05-31
R25AG067896	NIA MSTEM: Advancing Diversity in Aging Research through Undergraduate Education at the University of the District of Columbia	UNIVERSITY OF THE DISTRICT OF COLUMBIA	2025-05-31
R25AG069711	Neurocognitive Aging & Analytics Research Education (NAARE)	CALIFORNIA STATE UNIVERSITY FULLERTON	2025-05-31
R25AG076396	Networking and Expanding Undergraduate Research on the Neurobiology of Aging to Advance Diversity	UNIVERSITY OF FLORIDA	2025-05-31
R25AG076400	Gerontology Enriching MSTEM (GEMSTEM) to Enhance Diversity in Aging	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-05-31
R25DC021130	UMD-REACH (Research Equity and Access in Communication and Hearing)	UNIV OF MARYLAND, COLLEGE PARK	2025-05-31
R35GM118167-09S2	Cellular Decision Making	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	2025-05-31
R35GM119721-09S1	Diversity Supplement: Mechanistic Insights into Mammalian DNA Methylation	UNIVERSITY OF CALIFORNIA RIVERSIDE	2025-05-31
R36MH136807	Real-Time Monitoring of Relapse in Eating Disorders	UNIVERSITY OF LOUISVILLE	2025-05-31
U01HD115256-03S1	Integrating Responsive Feeding and Nutrition Security to Prevent Early Childhood Obesity in Food-Insecure Populations	UNIVERSITY OF NEVADA LAS VEGAS	2025-05-31
U24EY033269-04S1	Overcoming Barriers to retinal ganglion cell replacement in experimental glaucoma	INDIANA UNIVERSITY INDIANAPOLIS	2025-05-31
U54MD015959-03S1	Interdisciplinary Health Equity Research (IHER) Center	DELAWARE STATE UNIVERSITY	2025-05-31
F31AG076290	Elucidating the role of ER remodeling in aging of C. elegans	VANDERBILT UNIVERSITY	2025-06-02
F31AG076375	Women Living with HIV: Cognitive Impact of Estrogen Receptors, Inflammation, and Aging	VIRGINIA COMMONWEALTH UNIVERSITY	2025-06-02
F31AG082485	Neuropathological and spatial transcriptome brain maps in Octodon degus, a natural Alzheimer's disease rodent model	UNIVERSITY OF CALIFORNIA-IRVINE	2025-06-02
F31AG082506	Uncovering Mechanisms of Racial Inequalities in ADRD: Psychosocial Risk and Resilience Factors for White Matter Integrity	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-06-02
F31AG084149	The Influence of Lifetime Occupational Experience on Cognitive Trajectories Among Mexican Older Adults	UNIVERSITY OF TEXAS MED BR GALVESTON	2025-06-02
F31AG084195	Defining the Neuroprotective Mechanisms of Neuritin-1 in Cognitive Resilience to Alzheimer's Disease	UNIVERSITY OF ALABAMA AT BIRMINGHAM	2025-06-02
F31AG084238	Triggering the Selective Removal of Deleterious mtDNA Mutations from Mammalian Cells	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-06-02
F31AG084260	Astrocytic Na/H exchanger in AD astrogliosis	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-06-02
F31AG085937	Lifecourse Residential Segregation, Ethnic Enclaves and Risk and Resilience to ADRD in Diverse Cohorts	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-06-02
F31AG086073	Influences of Stigma and Social Support on Cognitive Function Among Older Women Living with Human Immunodeficiency Virus	YALE UNIVERSITY	2025-06-02
F31AG087599	Investigating physiological pathways modulating tau homeostasis: potential implications for Alzheimer's Disease and Related Dementia	JOHNS HOPKINS UNIVERSITY	2025-06-02
F31AG087648	Network drivers of regional vulnerability to early Alzheimer's disease pathology	UNIVERSITY OF CALIFORNIA BERKELEY	2025-06-02
F31AG087692	Mechanism of mitochondria-induced myokine activation and implications for healthy aging.	UPSTATE MEDICAL UNIVERSITY	2025-06-02
F31AG090048	Multidimensional Features of Socioeconomic Status, Brain Age, and the Potential Mediating Role of Cardiometabolic Health Among Mid and Late Life Adults	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-06-02
F31AG090063	Combining Chemical Biology and Machine Learning to Generate Reproducible Amyloid Fibrils	UNIVERSITY OF PENNSYLVANIA	2025-06-02
F31AG090069	Cell autonomous and cell non-autonomous roles for mitochondrial proline catabolism in health and longevity	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-06-02
F31AG090102	Lifespace mobility and cognitive decline after stroke	STANFORD UNIVERSITY	2025-06-02
F31DA062446	The glucocorticoid receptor as a top-down neuromolecular mechanism of inhibitory control	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-06-02
F31DC021353	Investigating the effects of olfactory critical period odorant exposure on the trace amine-associated receptor4 olfactory circuit	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	2025-06-02
F31DC021883	Spatiotemporal models of neural coding in the vestibular periphery	UNIVERSITY OF CHICAGO	2025-06-02
F32AG085960	Elucidating the Cell-Type Specific Neuroprotective Mechanisms in the APOE3 Christchurch Mutation in Alzheimer's Disease	WEILL MEDICAL COLL OF CORNELL UNIV	2025-06-02
F32AG085961	Investigation into transcriptomic control of dentate granule cell maturation and hyperexcitability in the apoE4 Alzheimer's Disease model	J. DAVID GLADSTONE INSTITUTES	2025-06-02
F32AG090054	A human organoid approach to understanding the role of the locus coeruleus in Alzheimer's disease	EMORY UNIVERSITY	2025-06-02

K00AG080847	Understanding the role of genetic admixture on Alzheimer's Disease risk in Latino Populations	UNIVERSITY OF COLORADO DENVER	2025-06-02
K00AG090127	Neurovascular Contributions to Cognitive and Mental health in Older Adult Critical Care Survivors	SPAULDING REHABILITATION HOSPITAL	2025-06-02
K99AG086524	Investigating TFEB as a critical node to improve proteostatic maintenance and skeletal muscle function with age	OKLAHOMA MEDICAL RESEARCH FOUNDATION	2025-06-02
K99AG088361	Patterns and Mechanisms Underlying Somatic Mutations Across Long-Lived Bats	UNIVERSITY OF CALIFORNIA BERKELEY	2025-06-02
K99AG088478	Non-invasive brain stimulation and neurovascular mechanisms of post-stroke cognitive impairment	UNIVERSITY OF OKLAHOMA HLTH SCIENCES CTR	2025-06-02
R00AG079117	The benefits of nicotinamide riboside upon cognition and sleep in older veterans	STATE UNIVERSITY OF NEW YORK AT BUFFALO	2025-06-02
R01DA059359	Sex Differences and The Influence of Ovarian Hormones on the Mechanisms that Promote Nicotine Withdrawal	UNIVERSITY OF TEXAS EL PASO	2025-06-02
R01DA059359-02S1	Sex Differences and The Influence of Ovarian Hormones on the Mechanisms that Promote Nicotine Withdrawal	UNIVERSITY OF TEXAS EL PASO	2025-06-02
R01DC012578-12S1	Reduction of Intracochlear Trauma and Fibrosis Using Dual Network, Zwitterionic Hydrogel Thin Films on Cochlear Implant Surfaces	UNIVERSITY OF IOWA	2025-06-02
R01DC019348-03S1	Bilateral integration of the auditory scene	LOUISIANA STATE UNIV A&M COL BATON ROUGE	2025-06-02
R01DC019943-03S1	Perception and Production of Emotional Prosody with Cochlear Implants	FATHER FLANAGAN'S BOYS' HOME	2025-06-02
R01DC021065	Exploring Pathways to Equitable Outcomes in Post-Stroke Aphasia and Dysphagia	UNIVERSITY OF FLORIDA	2025-06-02
R01DC021301	Characterizing the Effects of Chronic Substance Misuse on Auditory and Vestibular Function	TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER AT EL PASO	2025-06-02
R01DC021320	Hearing Loss, Prognosis, and Long-Term Impact of Otitis Media with Effusion in Children	FATHER FLANAGAN'S BOYS' HOME	2025-06-02
R01HD098097-04S1	Origins and Outcomes of Smartphone and Social Media Habits Across Development	TEMPLE UNIV OF THE COMMONWEALTH	2025-06-02
R25AG070244	Alabama State University-Auburn University Partnership to Promote Diversity in Aging Research	ALABAMA STATE UNIVERSITY	2025-06-02
R25DC021132	Enhancing Diverse Graduate Student Opportunities in Auditory and Vestibular Neuroscience	CREIGHTON UNIVERSITY	2025-06-02
R36AG087309	Lamin A/C is required for maintaining subsynaptic myonuclei integrity	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2025-06-02
R36AG087310	CA1 cell-type susceptibility in Alzheimer's	UNIVERSITY OF SOUTHERN CALIFORNIA	2025-06-02
R36AG087312	An Analysis Of The Multi-Level Factors That Impact Provision Of Emergency Medical Services To Hispanic Older Adults	UNIVERSITY OF CALIFORNIA LOS ANGELES	2025-06-02
R36AG088233	Development of N-acyl fluspirilene mediated proteasome enhancement for the treatment of neurodegenerative diseases	UNIVERSITY OF VIRGINIA	2025-06-02
R36AG088283	Exploring TMEM106B in Neurodegeneration: Protein Interaction and Fibril-induced Neurotoxicity	EMORY UNIVERSITY	2025-06-02
R36AG090801	Role of Hypoxia-inducible factor-2α signaling in age-induced bone loss	UNIVERSITY OF CALIFORNIA AT DAVIS	2025-06-02
R36AG090851	The role of networks and serious illness in Medicare Advantage disenrollment	VANDERBILT UNIVERSITY	2025-06-02
R36AG090854	After the Dust Settles: Changes in Local Healthcare Access and Utilization after Civil Unrest	BROWN UNIVERSITY	2025-06-02
R36AG090859	Investigating the fetal origins of myeloid-biased hematopoietic stem cells	STANFORD UNIVERSITY	2025-06-02
T32GM136503	G-RISE University of South Dakota	UNIVERSITY OF SOUTH DAKOTA	2025-06-02

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-WGY

SECOND SUPPLEMENTAL DECLARATION OF KATIE EDWARDS

I, Katie Edwards, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I provided a sworn declaration in this case dated April 24, 2025, ECF No. 38-20, and May 18, 2025, ECF No. 72-12. I offer this additional declaration as a supplement to those declarations.
2. I am offering this supplemental declaration in my individual capacity and not on behalf of my employer.
3. Since my May 18, 2025 declaration, I have been told by my institution—the University of Michigan—that they will be providing me with approximately $297,000 of bridge funding before the fiscal year ends in June 2025. The University of Michigan has emphasized to me that this is a one-time source of funding. I am immensely grateful to my institution for this support for our team and our work.
4. But unfortunately, my team's operating budget was over $200,000 *a month* before the NIH grant terminations, and this funding represents just a fraction of the approximately $2 million my lab spends each year on our work. As a result, although I fortunately do not anticipate having to make further cuts to staff or their hours for approximately two or three months, without additional funding at the level provided, I anticipate once again having to make significant cuts to staff jobs and hours around that time. That will not only negatively affect

their jobs and livelihoods, but it would also negatively affect the studies they work on, the participants they work with, and the populations who would be served by the research that will now be limited, stalled, or even fully cut off because of these terminations.

5. My co-investigators and I have continued to try to raise funds to replace the funding from the terminated NIH grants I mentioned in my April 24, 2025 declaration. But beyond the support from the University of Michigan described above, I have to date been able to raise only approximately $10,000 in funds to replace those terminated funds. To put that in perspective, that amount combined is less than half the amount of just the 2025-2026 fiscal year of the R01 grant (Project Number 5R01MD016384) I described in my May 18 declaration.
6. Because my co-investigators and I have to date been able to replace only a fraction of the amount provided by the terminated NIH grants, we have still not been able to resume collecting data for our studies, including the studies I described in detail in my April 24, 2025 declaration. We do not have sufficient funding to compensate participants long term, and I believe resuming our work just to shortly pause it again shortly thereafter would raise ethical concerns around our participants.
7. Instead, these limited funds will be used largely to help mitigate some of the fallout from these grant terminations. My team continues to respond to participants about any questions they have related to the study (*e.g.*, what happened with the study, if the study will resume) and to provide participants with connection to community resources. We are also performing a limited analysis of some of the data we have collected for the R01 grant I described in my May 18 declaration (Project Number 5R01MD016384). But that analysis (essentially, basic percentages)—based on incomplete datasets and without the staffing required to perform more complex statistical analyses—does not yield the kind of statistical significance or robust programmatic and policy recommendations that I set out to do when I first submitted the applications for these projects. We are performing basic analyses because we promised participants that they would receive a copy of the study results. Even though the results are incomplete and basic, we have decided to give participants something rather than nothing to uphold our promise to participants.
8. As I stated in my May 18, 2025 declaration, my co-investigators and I will keep trying to raise replacement funding. We are passionate about our field and work, and we are

committed to addressing the health equity needs of our study participants and the broader populations served by our research. But I still do not anticipate being able to raise nearly enough money to secure the amount of funding (millions of dollars) that we would have had with the NIH grants that have been terminated since March 2025.

9. Just as was the case in my May 18 declaration, I have continued to regularly work more than 15 hours a day, trying to juggle my research with my efforts to replace funding lost because of these NIH grant terminations. And because I have still had to focus so much on raising funds to make up for the loss of funding resulting from the termination of the NIH grants, the amount of time I can spend conducting my research, reviewing literature, or designing new studies to address the public health needs of the communities served by my research continues to be significantly reduced compared to the time before my grants were terminated.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this ___9th____ day of June, 2025.

Katie Edwards

_____

Katie Edwards