U.S. Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Ave. NW
Washington, DC 20530

Tel: 202-616-2875

January 2, 2026

VIA CM/ECF

Anastasia Dubrovsky, Clerk of Court
U.S. Court of Appeals for the First Circuit
John Joseph Moakley U.S. Courthouse
1 Courthouse Way, Suite 2500
Boston, MA 02210

RE: *American Public Health Association, et al. v. National Institutes of Health, et al.*, No. 25-1611 & *Commonwealth of Massachusetts, et al. v. Robert F. Kennedy, Jr., et al.*, No. 25-1612 (oral argument scheduled for January 6, 2026).

Dear Ms. Dubrovsky:

The government writes to notify the Court of two recent developments related to these cases.

First, on December 29, 2025, the parties filed a Joint Stipulation and Proposed Order (No. 25-cv-10814, Dkt. 192; No. 25-cv-10787, Dkt. 181) that would resolve the claims remaining in district court. For context, the district court bifurcated the litigation into two phases. Phase 1 addressed issues concerning the termination of existing grants, while Phase 2 addressed issues concerning the review of grant applications. The order currently under review was issued following the conclusion of Phase 1, and the proposed Joint Stipulations would resolve Phase 2.

Second, on December 12, 2025, the National Institutes of Health issued new Staff Guidance establishing procedures for reviewing grants for alignment with agency priorities.

Copies of the Joint Stipulations and the Staff Guidance are appended to this letter.

Sincerely,

s/
Benjamin C. Wei
Attorney

cc: Counsel of Record (via CM/ECF)

CERTIFICATE OF COMPLIANCE

This letter complies with the type-volume limit of Federal Rule of Appellate Procedure 28(j) because the body of the letter contains 138 words.

s/ Benjamin C. Wei
Benjamin C. Wei

CERTIFICATE OF SERVICE

I hereby certify that on January 2, 2026, I electronically filed the foregoing letter with the Clerk of the U.S. Court of Appeals for the First Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

s/ Benjamin C. Wei
Benjamin C. Wei

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, *et al.*,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., *et al.*,

Defendants.

No. 1:25-cv-10814-WGY

JOINT STIPULATION AND PROPOSED ORDER CONCERNING OUTSTANDING CLAIMS

All Plaintiffs[1] and all Defendants[2] in this action (collectively, the "Parties") hereby stipulate to—and respectfully request that the Court order—the resolution of the outstanding claims in this litigation subject to the following terms and conditions.

I. Background

1. Plaintiffs' Amended Complaint (ECF No. 75) alleges that Defendants violated the U.S. Constitution and the Administrative Procedure Act and engaged in *ultra vires* conduct by

[1] "Plaintiffs" are the Commonwealth of Massachusetts and the States of California, Maryland, Washington, Arizona, Colorado, Delaware, Hawai'i, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Rhode Island, and Wisconsin.

[2] "Defendants" are Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services; the United States Department of Health and Human Services; Jayanta Bhattacharya, in his official capacity as Director of the National Institutes of Health; the National Institutes of Health ("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.

refusing to consider and unreasonably delaying the review and disposition of applications for NIH grants submitted by Plaintiffs and Plaintiffs' subdivisions, instrumentalities, and institutions.

2. Defendants do not concede that Plaintiffs' claims are meritorious and do not admit any liability on those claims.

3. Notwithstanding the foregoing, Defendants will evaluate and render decisions on Plaintiffs' identified applications subject to the terms and conditions below. In exchange, Plaintiffs have agreed to the dismissal, without prejudice, of the outstanding claims described below, subject to the terms and conditions below.

II. Stipulation

The Parties hereby stipulate and agree that:

1. This stipulation relates to grant applications identified in the list of "Phase Two" applications that Plaintiffs provided to Defendants on August 15, 2025, as well as any grant applications identified on supplemental lists that Plaintiffs provided to Defendants on September 29, 2025,[3] provided that such listed applications were submitted to NIH on or before July 1, 2025, in the case of non-competing renewal or continuation applications, or on or before June 23, 2025, in the case of all other applications (the "Applications"). As used herein, the term "Applications" refers to applications of any type, including, without limitation, new applications, renewal applications, competing revision applications, extension applications, noncompeting continuation applications, resubmission applications, and applications for a change of organization status, recipient, or institute/center. For the avoidance of doubt, the Applications include those listed Applications for which NIH has not yet made a decision to withdraw, deny, or award the

[3] This stipulation does not apply to "Resulting Grant Terminations" listed in Exhibit A to the June 23, 2025, partial final judgment (ECF No. 151-1). Plaintiffs will not include any Resulting Grant Terminations listed in said Exhibit A in the lists that Plaintiffs have produced or will produce related to this stipulation.

Application; those listed Applications that were administratively withdrawn or denied pursuant to the withdrawal of a Notice of Funding Opportunity ("NOFO"); and those listed Applications that NIH considered but decided not to fund because of the Challenged Directives.[4]

2. Defendants will complete their consideration of the Applications in the ordinary course of NIH's scientific review process, without applying the Challenged Directives. Defendants will evaluate each application individually and in good faith.

3. Defendants will make decisions on all of the Applications consistent with 42 C.F.R., Chapter I—including, specifically, 42 C.F.R. § 52.5(b)—and provide notice to Plaintiffs of those decisions no later than the following dates:

a. For all Applications for non-competing renewal or continuation, Defendants will make a decision on the Application and provide notice to Plaintiffs of the decision by December 29, 2025, provided the proposed renewal date was on or before the date of entry of this stipulation.

b. For all Applications that were administratively withdrawn and/or denied because of the Challenged Directives ("Withdrawn or Denied Applications"), Defendants will make a decision on the Application and provide notice to Plaintiffs of the decision as follows:

i. For all Withdrawn or Denied Applications that, as of the effective date of this stipulation and order, have already undergone both study-section and advisory-council review, or have undergone study-section review and do not require advisory-council review, Defendants will make a decision on the Application and provide notice to Plaintiffs by January 12, 2026.

ii. For all Withdrawn or Denied Applications that, as of the effective date of this stipulation and order, have already been scored by a study section and that require, but have not yet undergone, advisory-council review, Defendants will make a decision on the Application and provide notice to Plaintiffs by April 14, 2026.

iii. For all other Withdrawn or Denied Applications, Defendants will make a decision on the Application and provide notice to Plaintiffs by July 31, 2026.

[4] The "Challenged Directives" are those directives named in, and vacated as stated in, the Rule 54(b) Final Judgment entered in this matter on June 23, 2025. *See* ECF No. 151, at 1 n. 1 and 2 ¶ I.

c. For all extension Applications or Applications for a change of organization status, recipient, or institute/center, Defendants will make a decision on the application in the ordinary course of NIH's scientific review process.

d. For all other Applications, the dates by which Defendants will make a decision on the Application and provide notice to Plaintiffs of their decision as follows:

i. For all Applications submitted on or before January 7, 2025, Defendants will make a decision on the Application within seven days of the filing of this Stipulation, and will provide notice to Plaintiffs of the decision by January 12, 2026;

ii. For all Applications submitted after January 7, 2025, and on or before May 7, 2025, Defendants will make a decision on the Application and provide notice to Plaintiffs of the decision by February 12, 2026; and

iii. For all Applications submitted after May 7, 2025, and on or before June 23, 2025, Defendants will make a decision on the Application and provide notice to Plaintiffs of the decision by April 14, 2026.

4. For any Applications that Defendants decide to grant, Defendants will inform the applicants of that grant through eRA Commons in the ordinary course.

5. To facilitate provision of notice, Plaintiffs provided Defendants with the application submission date, Advisory Council meeting date (if applicable), and the date of denial or withdrawal (if applicable) for Applications on October 14, 2025, to the extent that information was available to Plaintiffs by that date. The Notice Dates shall not apply to any Applications for which the Plaintiffs do not provide the preceding information.

6. Defendants stipulate and agree that the end of Federal Fiscal Year 2025 does not prevent Defendants from considering and/or awarding any of the Applications, subject to Congress's appropriation of funds to NIH.

7. Defendants will not deny any Application that was originally submitted to a NOFO that has since been unpublished because of the Challenged Directives on the basis that the NOFO has been unpublished.

8. Any Application submitted as an additional/alternative application to NIH

following the administrative withdrawal or denial of a listed Application, and which listed Application Defendants consider pursuant to this agreement, will not be penalized for being one of multiple simultaneously pending applications. Defendants will not deny any Application previously withdrawn or denied based on the Challenged Directives based on the applicant being time-barred for Early Stage Investigator status or any other time bars where the application was initially filed within proper time limits for the given NOFO.

9. Nothing in this stipulation commits NIH to ultimately award any specific Application, diminishes or enlarges NIH's discretion over the decision to award funding, or creates a final agency action where a final agency action would not otherwise exist. Nothing in this stipulation enlarges or diminishes any right or ability of any individual Plaintiff or applicant with respect to seeking review of the denial of any application.

10. On the basis of the Parties' stipulations, the Parties agree to the dismissal without prejudice of all outstanding claims that were not decided in the June 23, 2025, partial final judgment (ECF No. 151) and/or addressed in the July 2, 2025, findings of fact and conclusions of law (ECF No. 163). Notwithstanding the foregoing, the Parties agree that dismissal should issue and no further proceedings should occur with respect to the matters addressed in footnote 4 of the July 2, 2025, findings of fact and conclusions of law (ECF No. 163). Plaintiffs reserve the right to seek judgment on Counts 1 and/or 2 of the Amended Complaint consistent with Plaintiffs' view of the July 2, 2025, findings of fact and conclusions of law (ECF No. 163); Defendants reserve the right to oppose any such request for judgment.

11. The Parties will bear their own respective fees and costs.

12. The Court shall retain jurisdiction to enforce the terms of this stipulation, until such time as Defendants have considered and disposed of all Applications as stipulated.

III. Request for Relief

The parties respectfully request that the Court adopt and order the foregoing terms and conditions as set forth in the attached proposed order.

December 29, 2025

Respectfully submitted.

ANDREA JOY CAMPBELL
Attorney General of Massachusetts

/s/ *Gerard J. Cedrone*
Gerard J. Cedrone (BBO No. 699674)
Deputy State Solicitor
Vanessa A. Arslanian (BBO No. 688099)
State Trial Counsel
Phoebe M. Lockhart (BBO No. 709411)
Assistant Attorneys General
One Ashburton Place, 20th Floor
Boston, MA 02108
(617) 963-2282
gerard.cedrone@mass.gov

Counsel for the
Commonwealth of Massachusetts

BRETT A. SHUMATE
Assistant Attorney General
Civil Division

KIRK T. MANHARDT
Director

MICHAEL QUINN
Senior Litigation Counsel

/s/ Zachary Semple
ZACHARY C. SEMPLE
Trial Attorney
United States Department of Justice
Civil Division
1100 L Street, NW
Washington, D.C. 20005
Tel: (202) 353-5555
Fax: (202) 514-9163
E-mail: Zachary.C.Semple@usdoj.gov

/s/Anuj Khetarpal
ANUJ KHETARPAL
Assistant United States Attorney
United States Attorney's Office
1 Courthouse Way, Suite 9200
Boston, MA 02210

Attorneys for the United States

ROB BONTA
Attorney General of California

/s/ *Emilio Varanini*
Neli Palma
Senior Assistant Attorney General
Emilio Varanini*
Nimrod Pitsker Elias*
Supervising Deputy Attorneys General
Daniel D. Ambar*
Ketakee R. Kane*
Sophia TonNu*
Hilary Chan*
Deputy Attorneys General
455 Golden Gate Avenue
San Francisco, CA 94102
(415) 510-3541
emilio.varanini@doj.ca.gov

Counsel for the State of California
ANTHONY G. BROWN
Attorney General of Maryland

/s/ *James C. Luh*
Michael Drezner*
James C. Luh*
Senior Assistant Attorneys General
200 Saint Paul Place, 20th Floor
Baltimore, MD 21202
(410) 576-6959
mdrezner@oag.state.md.us

Counsel for the State of Maryland

NICHOLAS W. BROWN
Attorney General of Washington

/s/ *Andrew Hughes*
Andrew Hughes*
Tyler Roberts*
Assistant Attorneys General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744
andrew.hughes@atg.wa.gov

Counsel for the State of Washington

KRISTIN K. MAYES
Attorney General of Arizona

/s/ *Joshua G. Nomkin*
Joshua G. Nomkin*
Assistant Attorney General
2005 N. Central Avenue
Phoenix, AZ 85004
(602) 542-3333
joshua.nomkin@azag.gov

Counsel for the State of Arizona

PHILIP J. WEISER
Attorney General of Colorado

/s/ *Shannon Stevenson*
Shannon Stevenson*
Solicitor General
1300 Broadway, 10th Floor
Denver, CO 80203
(720) 508-6000
lauren.peach@coag.gov

Counsel for the State of Colorado

KATHLEEN JENNINGS
Attorney General of Delaware

/s/ *Vanessa L. Kassab*
Ian R. Liston*
Director of Impact Litigation
Vanessa L. Kassab*
Deputy Attorney General
820 N. French Street
Wilmington, DE 19801
(302) 683-8899
vanessa.kassab@delaware.gov

Counsel for the State of Delaware

ANNE E. LOPEZ
Attorney General of Hawai‘i

/s/ *Kaliko‘onālani D. Fernandes*
David D. Day*
Special Assistant to the Attorney General
Kaliko‘onālani D. Fernandes*
Solicitor General
425 Queen Street
Honolulu, HI 96813
(808) 586-1360
kaliko.d.fernandes@hawaii.gov

Counsel for the State of Hawai‘i

KEITH ELLISON
Attorney General of Minnesota

/s/ *Pete Farrell*
Peter J. Farrell*
Deputy Solicitor General
445 Minnesota Street, Suite 600
St. Paul, Minnesota, 55101
(651) 757-1424
peter.farrell@ag.state.mn.us

Counsel for the State of Minnesota

AARON D. FORD
Attorney General of Nevada

/s/ *Heidi Parry Stern*
Heidi Parry Stern*
Solicitor General
1 State of Nevada Way, Suite 100
Las Vegas, NV 89119
hstern@ag.nv.gov

Counsel for the State of Nevada

MATTHEW J. PLATKIN
Attorney General of New Jersey

/s/ *Nancy Trasande*
Nancy Trasande*
Bryce Hurst*
Deputy Attorneys General
124 Halsey Street, 5th Floor
Newark, NJ 07101
(609) 954-2368
nancy.trasande@law.njoag.gov

Counsel for the State of New Jersey

RAÚL TORREZ
Attorney General of New Mexico

/s/ *Astrid Carrete*
Astrid Carrete*
Assistant Attorney General
408 Galisteo Street
Santa Fe, NM 87501
(505) 270-4332
acarrete@nmdoj.gov

Counsel for the State of New Mexico

LETITIA JAMES
Attorney General of New York

/s/ *Rabia Muqaddam*
Rabia Muqaddam*
Special Counsel for Federal Initiatives
Molly Thomas-Jensen*
Special Counsel
28 Liberty Street
New York, NY 10005
(929) 638-0447
rabia.muqaddam@ag.ny.gov

Counsel for the State of New York

DAN RAYFIELD
Attorney General of Oregon

/s/ *Christina L. Beatty-Walters*
Christina L. Beatty-Walters*
Leanne E. Hartmann (BBO No. 667852)
Senior Assistant Attorneys General
100 SW Market Street
Portland, OR 97201
(971) 673-1880
tina.beattywalters@doj.oregon.gov

Counsel for the State of Oregon

PETER F. NERONHA
Attorney General of Rhode Island

/s/ *Jordan Broadbent*
Jordan Broadbent*
Special Assistant Attorney General
150 South Main Street
Providence, RI 02903
(401) 274-4400, Ext. 2060
jbroadbent@riag.ri.gov

Counsel for the State of Rhode Island

JOSHUA L. KAUL
Attorney General of Wisconsin

/s/ *Lynn K. Lodahl*
Lynn K. Lodahl*
Assistant Attorney General
17 West Main Street
P.O. Box 7857
Madison, WI 53707
(608) 264-6219
lodahllk@doj.state.wi.us

Counsel for the State of Wisconsin

*admitted *pro hac vice*

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, *et al.*,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., *et al.*,

Defendants.

No. 1:25-cv-10814-WGY

[PROPOSED] ORDER CONCERNING REMAINING CLAIMS

Upon consideration of the parties' joint stipulation and request for relief regarding the remaining claims of this litigation ("Joint Stipulation"), pursuant to Federal Rule of Civil Procedure 41(a)(2), it is hereby **ORDERED** that:

I. Plaintiffs and Defendants shall comply with and carry out their respective obligations as set forth in Part II of the parties' Joint Stipulation.

II. Counts 4, 5, 6, 7, and 8 of the Amended Complaint (ECF No. 75) are dismissed without prejudice. All Phase Two trial dates and/or Phase Two pretrial deadlines are hereby vacated.

III. The Court shall retain jurisdiction to enforce the terms of this order and the parties' Joint Stipulation until such time as Defendants have considered and disposed of all identified applications as set forth in the Joint Stipulation.

IN THE 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-WGY

JOINT STIPULATION AND PROPOSED
ORDER CONCERNING OUTSTANDING CLAIMS

APHA Plaintiffs[1] and all Defendants[2] in this action (collectively, the "Parties") hereby stipulate to—and respectfully request that the Court order—the resolution of the outstanding claims in this litigation subject to the following terms and conditions.

I. Background

1. APHA Plaintiffs' Complaint (ECF No. 1) alleges that Defendants violated the Administrative Procedure Act[3] by refusing to consider and unreasonably delaying the review and disposition of applications for NIH grants submitted by APHA Plaintiffs and APHA Plaintiffs' members.[4]

2. Defendants do not concede that APHA Plaintiffs' claims are meritorious and do not admit any liability on those claims.

3. Notwithstanding the foregoing, Defendants will evaluate and render decisions on APHA Plaintiffs' identified applications subject to the terms and conditions below. In exchange, APHA Plaintiffs have agreed to the dismissal, without prejudice, of the outstanding claims described below, subject to the terms and conditions below.

II. Stipulation

The Parties hereby stipulate and agree that:

1. This stipulation relates to grant applications identified in the list of "Phase Two"

[1] "APHA Plaintiffs" are the 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.

[2] "Defendants" are the National Institutes of Health (NIH); Jay Bhattacharya, in his official capacity as Director of the National Institutes of Health; the United States Department of Health and Human Services; and Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services.

[3] APHA Plaintiffs also alleged, among other claims, constitutional claims, which were dismissed without prejudice. (ECF No. 84).

[4] A member of Plaintiffs APHA or UAW is defined in the Proposed Order and Judgment for Plaintiffs' preliminary injunction ECF No. 103-1 ¶ 4(a).

applications that APHA Plaintiffs provided to Defendants on June 30, 2025, as well as any grant applications identified on supplemental lists that APHA Plaintiffs provided to Defendants on or before September 29, 2025,[5] provided that such listed applications were submitted to NIH on or before July 1, 2025, in the case of non-competing renewal or continuation applications, or on or before June 23, 2025, in the case of all other applications (the "Applications"). As used herein, the term "Applications" refers to applications of any type, including, without limitation, new applications, renewal applications, competing revision applications, extension applications, noncompeting continuation applications, resubmission applications, and applications for a change of organization status, recipient, or institute/center. For the avoidance of doubt, the Applications include those listed Applications for which NIH has not yet made a decision to withdraw, deny, or award the Application; those listed Applications that were administratively withdrawn or denied pursuant to the withdrawal of a Notice of Funding Opportunity ("NOFO"); and those listed Applications that NIH considered but decided not to fund because of the Challenged Directives.[6]

a. On September 29, 2025, APHA Plaintiffs certified under oath that an APHA Plaintiff or member of Plaintiffs APHA or UAW is associated with each of the Applications.

2. Defendants will complete their consideration of the Applications in the ordinary course of NIH's scientific review process, without applying the Challenged Directives. Defendants will evaluate each application individually and in good faith.

3. Notwithstanding the timing limitations in Subparagraph II.1, Defendants shall not

[5] This stipulation does not apply to "Resulting Grant Terminations" listed in Exhibits A and B to the June 23, 2025, partial final judgment (ECF Nos. 138-1 and 138-2). APHA Plaintiffs will not include any Resulting Grant Terminations listed in said Exhibits A and B in the lists that APHA Plaintiffs have produced or will produce related to this stipulation.
[6] The "Challenged Directives" are those directives named in, and vacated as stated in, the Rule 54(b) Final Judgment entered in this matter on June 23, 2025. *See* ECF No. 138, at 2 ¶ 1 & n. 1 and 2 ¶ 2.

apply the Challenged Directives to any application listed in the spreadsheet regardless of the date it was submitted and shall review those applications in the ordinary course of NIH's scientific review process.

4. Defendants will make decisions on all of the Applications consistent with 42 C.F.R., Chapter I—including, specifically, 42 C.F.R. § 52.5(b)—and provide notice to APHA Plaintiffs of those decisions no later than the following dates:

a. For all Applications for non-competing renewal or continuation, Defendants will make a decision on the Application and provide notice to APHA Plaintiffs of the decision by December 29, 2025, provided the proposed renewal date was on or before the date of entry of this stipulation.

b. For all Applications that were administratively withdrawn and/or denied because of the Challenged Directives ("Withdrawn or Denied Applications"), Defendants will make a decision on the Application and provide notice to APHA Plaintiffs of the decision as follows:

i. For all Withdrawn or Denied Applications that, as of the effective date of this stipulation and order, have already undergone both study-section and advisory-council review, or have undergone study-section review and do not require advisory-council review, Defendants will make a decision on the Application and provide notice to APHA Plaintiffs by January 12, 2026.

ii. For all Withdrawn or Denied Applications that, as of the effective date of this stipulation and order, have already been scored by a study section and that require, but have not yet undergone, advisory-council review, Defendants will make a decision on the Application and provide notice to APHA Plaintiffs by April 14, 2026.

iii. For all other Withdrawn or Denied Applications, Defendants will make a decision on the Application and provide notice to APHA Plaintiffs by July 31, 2026.

c. For all extension Applications or Applications for a change of organization status, recipient, or institute/center, Defendants will make a decision on the application in the ordinary course of NIH's scientific review process.

d. For all other Applications, the dates by which Defendants will make a decision on the Application and provide notice to APHA Plaintiffs of their decision are as follows:

i. For all Applications submitted on or before January 7, 2025, Defendants will make a decision on the Application within seven days of the filing of this stipulation, and will provide notice to APHA Plaintiffs of the decision by January 12, 2026;

ii. For all Applications submitted after January 7, 2025, and on or before May 7, 2025, Defendants will make a decision on the Application and provide notice to APHA Plaintiffs of the decision by February 12, 2026; and

iii. For all Applications submitted after May 7, 2025 and on or before June 23, 2025, Defendants will make a decision on the Application and provide notice to APHA Plaintiffs of the decision by April 14, 2026.

5. For any Applications that Defendants decide to grant, Defendants will inform the applicants of that grant through eRA Commons in the ordinary course.

6. To facilitate provision of notice, APHA Plaintiffs provided Defendants with the application submission date, Advisory Council meeting date (if applicable), and the date of withdrawal (if applicable) for Applications on October 14, 2025, to the extent that information was available to APHA Plaintiffs by that date. The requirements set out in Subparagraph II.4 for Defendants to provide notice to APHA Plaintiffs by a certain date shall not apply to any Applications for which APHA Plaintiffs did not provide the preceding information or to any Application submitted after July 1, 2025, in the case of non-competing renewal or continuation applications, or after June 23, 2025, in the case of all other applications.

7. Defendants stipulate and agree that the end of Federal Fiscal Year 2025 does not prevent Defendants from considering and/or awarding any of the Applications, subject to Congress's appropriation of funds to NIH.

8. Defendants will not deny any Application that was originally submitted to a NOFO that has since been unpublished because of the Challenged Directives on the basis that the NOFO has been unpublished.

9. Any application submitted as an additional/alternative application to NIH following

the administrative withdrawal or denial of a listed Application, and which listed Application Defendants consider pursuant to this agreement, will not be penalized for being one of multiple simultaneously pending applications. Defendants will not deny any Application previously withdrawn or denied based on the Challenged Directives based on the applicant being time-barred for Early Stage Investigator status or any other time bars where the application was initially filed within proper time limits for the given NOFO.

10. Nothing in this stipulation commits NIH to ultimately award any specific Application, diminishes or enlarges NIH's discretion over the decision to award funding, or creates a final agency action where a final agency action would not otherwise exist. Nothing in this stipulation enlarges or diminishes any right or ability of any individual Plaintiff or applicant with respect to seeking review of the denial of any application.

11. On the basis of the Parties' stipulations, the Parties agree to the dismissal without prejudice of all outstanding claims that were not decided in the June 23, 2025, partial final judgment (ECF No. 138) and/or addressed in the July 2, 2025, findings of fact and conclusions of law (ECF No. 151). Plaintiffs further agree that they have not raised any claims of discrimination and no further proceedings in this case should occur with respect to the matters addressed in footnote 4 of the July 2, 2025, findings of fact and conclusions of law (ECF No. 151). Plaintiffs reserve the right to seek judgment on Counts II and/or III of the Complaint consistent with Plaintiffs' view of the July 2, 2025, findings of fact and conclusions of law (ECF No. 151); Defendants reserve the right to oppose any such request for judgment.

12. The Parties will bear their own respective fees and costs incurred as part of drafting and litigating the documents in this case found at Docket Nos. 130, 131, 132, 149, 140, 153, 161, 163, 167,169, 170. The Parties shall also bear their own respective costs incurred negotiating this

Stipulation.

13. The Court shall retain jurisdiction to enforce the terms of this stipulation, until such time as Defendants have considered and disposed of all Applications as stipulated.

III. Request for Relief

The parties respectfully request that the Court adopt and order the foregoing terms and conditions as set forth in the attached proposed order.

December 29, 2025

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,

By their attorneys,

/s/ *Jennifer M. Herrmann*
Jessie J. Rossman
Suzanne Schlossberg
Jennifer M. Herrmann
American Civil Liberties Union Foundation of Massachusetts, Inc.
One Center Plaza, Suite 850
Boston, MA 02018
617-482-3170
jrossman@aclum.org
sschlossberg@aclum.org
jherrmann@aclum.org

Olga Akselrod
Rachel Meeropol
Alexis Agathocleous
Alejandro Ortiz
American Civil Liberties Union Foundation
125 Broad Street, 18th Floor
New York, NY 10004
212-549-2659

Respectfully submitted.

BRETT A. SHUMATE
Assistant Attorney General
Civil Division

LEAH B. FOLEY
United States Attorney

KIRK T. MANHARDT
Director

MICHAEL QUINN
Senior Litigation Counsel

/s/ Zachary Semple
ZACHARY C. SEMPLE
Trial Attorney
United States Department of Justice
Civil Division
1100 L Street, NW
Washington, D.C. 20005
Tel: (202) 353-5555
Fax: (202) 514-9163
E-mail: Zachary.C.Semple@usdoj.gov

/s/Anuj Khetarpal
ANUJ KHETARPAL
Assistant United States Attorney
United States Attorney's Office
1 Courthouse Way, Suite 9200
Boston, MA 02210

Attorneys for the United States

oakselrod@aclu.org
rmeeropol@aclu.org
aagathocleous@aclu.org
ortiza@aclu.org

Matthew D. Brinckerhoff
Ilann M. Maazel
Max Selver
Sydney Zazzaro
Emery Celli Brinckerhoff Abady Ward & Maazel LLP
One Rockefeller Plaza, 8th Floor
New York, New York 10020
(212) 763-5000
mbrinckerhoff@ecbawm.com
imaazel@ecbawm.com
mselver@ecbawm.com
szazzaro@ecbawm.com

Shalini Goel Agarwal
Emily Gilman
Protect Democracy Project
2020 Pennsylvania Ave., NW,
Ste. 163
Washington, DC 20006
202-579-4582
shalini.agarwal@protectdemocracy.org
emily.gilman@protectdemocracy.org

Michel-Ange Desruisseaux
Protect Democracy Project
82 Nassau Street, #601
New York, NY 10038
202-579-4582
michel-ange.desruisseaux@
protectdemocracy.org

Kenneth Parreno
Protect Democracy Project
15 Main Street, Suite 312
Watertown, MA 02472
202-579-4582
kenneth.parreno@protectdemocracy.org

Lisa S. Mankofsky
Oscar Heanue

Center for Science in the Public Interest
1250 I St., NW, Suite 500
Washington, DC 20005
202-777-8381
lmankofsky@cspinet.org
oheanue@cspinet.org

IN THE 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-WGY

[PROPOSED] ORDER CONCERNING REMAINING CLAIMS

Upon consideration of the parties' joint stipulation and request for relief regarding the remaining claims of this litigation ("Joint Stipulation"), pursuant to Federal Rule of Civil Procedure 41(a)(2), it is hereby **ORDERED** that:

I. APHA Plaintiffs and Defendants shall comply with and carry out their respective obligations as set forth in Part II of the parties' Joint Stipulation.

II. Count I.B, the portions of Count III relating to applicants, and Count V of the APHA Plaintiffs' Complaint (ECF No. 1) are dismissed without prejudice. All Phase Two trial dates and/or Phase Two pretrial deadlines are hereby vacated.

III. The Court shall retain jurisdiction to enforce the terms of this order and the parties' Joint Stipulation until such time as Defendants have considered and disposed of all identified applications as set forth in the Joint Stipulation.

Staff Guidance – Reviewing Grants for Priority Alignment
Issue Date: December 12, 2025

This Staff Guidance establishes procedures for the NIH Institutes and Centers (ICs) to review grants for alignment with the priorities set forth in the August 15, 2025, NIH Director's Priorities Statement, "Advancing NIH's Mission Through a Unified Strategy" and its addenda, if any ("Priorities Statement"). See https://www.nih.gov/about-nih/nih-director/statements/advancing-nihs-mission-through-unified-strategy. The August 15, 2025, Priorities Statement superseded the February 21, 2025, statement of the Acting NIH Director, "Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards." The February 21, 2025, statement is no longer in effect. This Staff Guidance supersedes the Staff Guidance issued by OPERA in March 2025 through May 2025 that implemented the February 21, 2025, statement. The prior Staff Guidance is no longer in effect.

Applicability

This Staff Guidance applies to all existing and new awards for grants, cooperative agreements and Other Transactions; however, it does not apply to any grant that is flagged in eRA as the subject of litigation or court orders. ICOs must not subject those grants to the priority alignment policies and procedures described below. Additional guidance will be provided regarding these flags.

Background

On August 15, 2025, the NIH Director issued a Statement of NIH Priorities to provide the overall direction of NIH, to establish and implement general policies respecting the management and operation of NIH programs and activities, and to coordinate and oversee the operation of NIH's Institutes, Centers, and Offices.

Beginning in FY26 ICs must review their full portfolio of ongoing awards for alignment with these NIH August 15, 2025, priorities (and any subsequent addenda). No competing or non-competing awards may be issued until the project has been assessed, and all areas of non-alignment have been addressed.

To assess projects, ICOs must first conduct an evaluation using a computational text analysis tool to scan for terms that may potentially be associated with misalignment with the agency's priorities.

- This review must be conducted for **all** competing applications to be awarded and ongoing projects in the ICO's portfolio, including projects currently in a no-cost extension.
- If the initial text analysis review finds no concerns, ICOs may proceed with the award following standard procedures.
- Any projects that are identified by the text analysis tool as potentially unaligned with agency priorities must be manually reviewed, renegotiated or, if renegotiation is not possible, terminated as outlined below.
- Grants should be reviewed by ICO staff on a case-by-case basis, according to the principles described below and without reference to whether or not the NOFOs under which they were funded are still active. The state of the NOFO can be used as part of the automated scanning process (see below) to help identify applications and grants that are potentially out of alignment because they came in under a NOFO that was taken down and might contain elements that need to be remediated (e.g., Recruitment Plans, etc.). However, after the scanning process is completed, staff should examine each flagged application or grant individually.

Procedures

Project Assessment

- As projects approach the next Type 5 or a Type 1 or 2 is moving to To Be Paid status, ICOs must assess each project for alignment with NIH priorities.
- ICOs should review awards that are nearing the end of the project period and may be preparing to initiate no-cost extensions to determine if the extension should be allowed.
- ICOs are responsible for their respective portfolio reviews.
- First, the ICO must use the computational text analysis tool to evaluate the award. This tool is currently maintained for ICO use by NIGMS and looks for terms that have been found to be associated with grants that are not aligned with the NIH's priorities.
- If the text analysis tool identifies any potential aspects of the project that do not align with NIH priorities, the appropriate ICO staff must manually evaluate the award using the August 15, 2025 NIH Director's Statement of NIH Priorities and its addenda, if any. The determinations must be linked to the appropriate priority and the ICO must document the specific areas of the project that do not align with the NIH's priorities in their determination. A few clarifying points to note are:
    - Pay particular attention to the use in grants of poorly defined, non-scientific or subjective terms and variables, as defined in the August 15, 2025 NIH Director's Statement of NIH Priorities and its addenda, to frame or justify the research. Frequent examples are "health equity" and "structural racism." If these can be replaced with well-defined, scientific concepts that have objective and measurable variables, then the grant can likely be renegotiated to focus on those instead. For example, framing around "health equity" might be refocused to emphasize studying and ameliorating a particular health disparity. In some cases, however, the entire premise of the grant relies on subjective or poorly defined, non-scientific terms, in which case it might not be possible to renegotiate it.
    - Health disparities research is within the NIH's priorities as long as it is scientifically justified and the interventions or potential interventions relate to areas that can be directly influenced by healthcare or biomedical science. Examples of areas that would not be directly influenced by healthcare or biomedical science include (but are not limited to) poverty, employment, and immigration.
    - NIH-funded research can focus on or include specific populations - such as racial or SG minorities - if it is scientifically justified. For example, the disease/condition could be more prevalent in a certain group, or that group is not currently sufficiently represented in studies of a potential therapeutic to make conclusions about its efficacy or side effects in the group.
        - Specific groups included in research studies should be described using clearly defined, standardized terms. For racial and ethnic groups, OMB's reporting categories (SPD 15) should be used: https://www.census.gov/newsroom/blogs/random-samplings/2024/04/updates-race-ethnicity-standards.html. Terms such as LatinX

that are not consistent with these categories should not be used. Gender should not be used as a synonym for biological sex.

- A clinical study that says it plans to increase the diversity of its patient base is within the NIH's priorities as long as the need for increased patient diversity is scientifically justified.
- Grants intended to increase workforce diversity by granting preferential treatment to individuals based on protected characteristics such as race or ethnicity are not consistent with the NIH's priorities. If they are focused on trainees early in their careers (e.g., undergraduates) they can often be renegotiated because their goals are not tailored to specific groups. Programs to promote diversity in the workforce at later careers stages, such as faculty members, are often harder to renegotiate particularly if they are tailored towards specific groups (e.g., underrepresented populations). Limiting program eligibility or giving preferential eligibility to members of specific groups based on protected statuses such as race, ethnicity or sex is not consistent with the NIH's priorities and is likely to be legally problematic.
    - Grants that are aimed at building research capacity at certain types of institutions, states or regions are within the NIH's priorities if there is a clear need and justification. Examples include resource-limited institutions and IDeA states.
    - Grants supporting research involving federally recognized American Indian or Alaska Native Tribes are within the NIH's priorities.
- Direct foreign awards must be strongly justified in terms of providing unusual talent, resources, populations, or environmental conditions that are not readily available in the United States and must provide the opportunity to significantly advance health sciences in the U.S.
- Please keep an eye out for grants that are overtly political in nature – for instance, take a clear political side rather than adopting a neutral, scientific approach to answering a question – and for grants that contain work that could be construed as lobbying. These grants could violate the NIH's Terms and Conditions of Award: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.5_lobbying_-_appropriation_prohibition.htm?Highlight=lobbying.

- The ICO must ensure the award program aligns with the granting authorities (can consult OPERA as needed). See Item 13 on page one of the Notice of Award. The most common granting authorities that are used include but are not limited to:
    - Research, Career Development, Conference Grants, Research Education Awards: 42 USC 241; 42 CFR 52
    - Training and Fellowship: 42 USC 288; 42 CFR 66
    - NIEHS Hazardous Materials Training: 42 USC 9660a; 42 CFR 65
    - International Research Training Grants:42 U.S.C. 287b; 42 C.F.R. Part 63a
- Internal approval processes may be managed at the ICO level, as long as all decisions are fully documented in the grant file.

- If the ICO determines that the award fully aligns with NIH priorities, the ICO may proceed with issuing the award.
- After the manual review, any projects that are identified as potentially unaligned with agency priories must be renegotiated to bring them into alignment or, if renegotiation is not possible, terminated or not awarded.

Renegotiation

- Please remember that the ICs will need to substantively renegotiate the projects with the recipients; they are not just "changing words." In most cases, some underlying components of the work also need to be altered. Once these renegotiations are done, all changes in scope that were agreed upon by NIH and the Authorized Organizational Representatives (AOR) become new terms and conditions of award, and the recipient must comply with those changes. If NIH discovers that recipients and/or subrecipients have not complied with the new terms and conditions of their award, NIH can immediately take an enforcement action under 2 CFR 200, which includes termination for non-compliance under 2 CFR 200.340(a)(1).
- For awards that can be renegotiated, ICOs must document their determination in a decision memo that outlines the specific areas of the project that do not align with the NIH priorities, and the actions taken to resolve them. In general, 2-3 sentences should suffice for this memo.
- To initiate the updates to the project, the Program Official (PO) must send a written request to the recipient Authorized Organization Representative (AOR) and copy the Grants Management Specialist (GMS).
- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit revised documents as appropriate (e.g., face page, specific aims, abstract, budget, title, etc.) via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO approves the renegotiation, the ICO must upload the updated documentation into the Additions for GM section of the grant folder. 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.
- All awards that are identified as out of alignment with NIH priorities **must** be renegotiated before the competing award or the next Type 5 is issued.
- Internal approvals may be managed at the ICO level, as long as all decisions are fully documented in the grant file.
- After NIH and the AOR complete the negotiations, the ICO releases the award. The revised NOA must include a term of award stating that award has been renegotiated, and the recipient must comply with the changes. If the ICO determines that recipients have not complied with the new terms and conditions of their award, the ICO must contact OPERA to determine appropriate remedies for noncompliance (See NIH GPS 8.5.2).
- Grants that have been released for award by the ICOs will then be scanned by eRA.
    - Grants that are flagged by eRA will be sent to the DDER Review Team for further assessment.
    - Reviewers will assess each flagged grant and return a spreadsheet to the IC noting the following categories:
        - In alignment with the NIH's priorities (no highlights).
        - Partially out of alignment and needs additional renegotiations to be in alignment (highlighted in yellow). ICOs must start/restart the renegotiation process to address the issues identified by the DDER Review Team.

    - Fully out of alignment and unlikely to be renegotiable (highlighted in red). These are expected to be rare and will be sent to OER for a final determination, to be handled centrally.
  - ICOs will be instructed to perform "Stop Release" action for all highlighted grants and eRA will put highlighted grants (yellow or red) on hold until resolved.

Termination

- For awards that are fully out of alignment with NIH priorities and cannot be renegotiated, the award must be terminated. Prior to terminating, ICOs must send OPERA Leadership and copy Jon Lorsch the information identified under Appendix 1 for each award that the IC proposes to terminate. The required information outlines the specific areas of the project that do not align with the NIH priorities, why negotiation is not possible, and an assessment of countervailing reliance factors.
- OPERA will then prepare a draft decision memo on behalf the IC that analyzes each proposed termination and will submit the draft to the IC for concurrence. Once the IC concurs, the memo will be transmitted on behalf of the IC to the NIH Director through Jon Lorsch. The NIH Director must approve the termination before the ICO may proceed with termination.
- OER has updated the NOA templates for all awards issued after October 1 to state that the awards are subject to 2 CFR 200, and to specify the termination provisions of 2 CFR 200.340, including .340(a)(4), which permits terminations for non-alignment with agency priorities. Therefore, prior to terminating the project, the ICO must first ensure that the current NOA being terminated contains this new language prior to proceeding with terminating the award. If it does not, then the IC must wait until the next budget period to issue a NOA (i.e., the next Type 5 award) which will include the updated termination provision.
- If the award is in its final year, the ICO must notify the recipient that NIH will not allow the first automatic no-cost extension (NCE) and notify OPERA so that OPERA can work with eRA to remove the automatic notifications to the recipient. IC's may not terminate the award but must allow it to end naturally.
- For awards currently in an NCE, the ICO must notify the recipient that NIH will not allow any additional NCEs and notify OPERA Leadership. OPERA will place a red bar to award to prevent future NCEs.
- When issuing the NOA to terminate the award, the ICO must use the "Terminated – No longer effectuates the program goals or agency priorities" post-award revision type.

Appendix 1– Information to Provide OPERA for a Decision Analysis

1. IC Designated Official

2. Award Number and Title

3. Cite relevant granting authority (e.g., 42 USC 241and 284 as implemented under 42 CFR Part 52).

4. Insert language from granting authority that outlines the purpose of the award program. Select one of the following options, as applicable. If ICOs identify any activities not covered here, contact OPERA.:

a. Research projects: the statutes authorize NIH to support research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases. Research Project Grants offer support to U.S. domestic institutions as well as foreign entities/components, where appropriate, and are NIHs most commonly used grant for independent research projects.
b. NRSA Training and Fellowship Awards: The statute authorizes NIH to make grants to public and nonprofit private institutions to enable such institutions to make National Research Service Awards (NRSA) for research (and training to undertake biomedical and behavioral research) in the matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health are directed. The purpose of the Ruth L. Kirschstein NRSA Individual Predoctoral (Parent F31) award is to enable promising predoctoral students to obtain individualized, mentored research training from appropriate faculty sponsors while conducting biomedical research in scientific health-related fields relevant to the missions of the participating NIH Institutes and Centers. The proposed mentored research training must address the candidate's identified research training and career goals and enhance the candidate's potential to successfully transition to the next phase of their biomedical research career.
c. International Research Training Grants: The statute authorizes NIH to provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences; and provide postdoctorate fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries. The purpose of this program is to support research training programs for US and foreign professionals and students to strengthen global health research and international research collaboration.

5. Describe the specific award that is being terminated. Include award objectives and any other specific details that are relevant to the termination decision, citing the specific priorities in the NIH Director's statement.

6. Budget period start and end date.

7. Project period start and end date.

8. Confirm that the award states the following:

   This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, by accepting an NIH award, the recipient agrees that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates the program goals or agency priorities, in line with 2 CFR 200.340(a)(4).

   Any term or condition in this Notice of Award, including those incorporated by reference, that NIH is enjoined by court order from imposing or enforcing, shall not apply or be enforced as to any recipient or subrecipient to which that court order applies and while that court order is in effect.

9. Quote the relevant language from the August 15, 2025, priority statement that relates to the nonalignment identified under the award

10. Describe how the award is not in alignment with agency priorities for NIH. Be as specific as possible. If there are aspects of the award that might weigh in favor of not terminating it (e.g., an aspect might support advancement of a different agency priority), address how terminating the award overall outweighs those aspects.

11. Describe why renegotiation is not possible.

12. Address reliance interests of recipients, beneficiaries of the award program and/or award, and the public generally. Reliance interests include reasonable actions the grantees took based on their expectations for continuation of the award, such as hiring or student recruitment. Also address potential impacts on public health and subrecipients.