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, DECLARATION, AND PERMANENT INJUNCTION

Upon consideration of Plaintiffs'[1] motion for a preliminary injunction; the memorandum of law, declarations, and evidence submitted in support thereof and in opposition thereto; the certified administrative record filed by Defendants;[2] the parties' merits briefs; and the hearing on the merits, and in accordance with Federal Rule of Civil Procedure 65(a)(2), the Court hereby disposes of Plaintiffs' claims in Counts 1–6 and 8 of the Amended Complaint (ECF No. 75)

[1] "Plaintiffs" refers collectively to the Commonwealth of Massachusetts and the States of California, Maryland, Washington, Arizona, Delaware, Hawai'i, Colorado, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Rhode Island, and Wisconsin. As used in this order, the term "Plaintiffs" includes the foregoing states' instrumentalities, public colleges and universities, subdivisions, counties, and municipalities. The State of Colorado did not join in Plaintiffs' motion for a preliminary injunction but is otherwise a plaintiff in this action and has joined in Plaintiffs' request for final relief.

[2] "Defendants" refers collectively to 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, 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.

pertaining to the legality of the below-defined Challenged Directives, Agency Priorities Regulation, and associated grant terminations as follows:

I. It is hereby **ORDERED** and **DECLARED** that the following directives, referred to collectively as the "Challenged Directives," constitute final agency actions that (1) violate the Administrative Procedure Act, 5 U.S.C. §706(2), because 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; (2) violate the Spending Clause and separation-of-powers principles of the U.S. Constitution, and (3) constitute *ultra vires* Executive action:

a. The February 10, 2025, directive promulgated by the Acting Secretary of Health and Human Services entitled "Secretarial Directive on DEI-Related Funding" as reproduced at pages 4–5 of the certified administrative record and incorporated *infra* as **Exhibit A** (Secretarial Directive);

b. The February 12, 2025, memorandum issued by Michael Lauer entitled "NIH Review of Agency Priorities Based on the New Administration's Goals" as reproduced at page 9 of the certified administrative record and incorporated *infra* as **Exhibit B** (Lauer Memorandum);

c. The February 13, 2025, memorandum issued by Dr. Lauer entitled "Supplemental Guidance" as reproduced at page 16 of the certified administrative record and incorporated *infra* as **Exhibit C** (Supplemental Lauer Memorandum);

d. The February 21, 2025, memorandum issued by Matthew Memoli entitled "Directive on NIH Priorities" regarding "Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards" as reproduced at pages 2930–2931 of the certified administrative record and incorporated *infra* as **Exhibit D** (Memoli Directive);

e. The March 4, 2025, directive issued by NIH entitled "Award Assessments for Alignment with Agency Priorities—March 2025" as reproduced at pages 2135–2172 of the certified administrative record and incorporated *infra* as **Exhibit E** (Priorities Directive);

f. The March 13, 2025, directive issued by Michelle Bulls entitled "Award Revision Guidance and List of Terminated Grants via letter on 3/12" as

reproduced at pages 1957–1968 of the certified administrative record and incorporated *infra* as **Exhibit F** (Awarded Revision Guidance);

g. Subsequent revisions to the Priorities Directive reproduced at pages 3216–3350, 3351–3379, and 3517–3581 of the certified administrative record and incorporated *infra* as **Exhibits G, H**, and **I**, respectively (Revised Priorities Directives); and

h. Any other directive, including non-public or undisclosed directives, that direct or effectuate the termination of previously awarded NIH grants, on the grounds that the opportunities or grants relate to one or more of the following topics as identified and described at page 3536 of the certified administrative record (which is incorporated *infra* in **Exhibit I**): China, DEI, transgender issues or gender-affirming care, vaccine hesitancy, COVID-19, climate change, or influencing public opinion.

II. It is hereby **ORDERED** and **DECLARED** that 2 C.F.R. §200.340(a)(2) (2020) and 2 C.F.R. §200.340(a)(4) (2024) (the "Agency-Priorities Regulation") do not independently permit or authorize termination of awarded grants based on agency priorities identified after the issuance of the notice of award for the award in question.

III. It is hereby **ORDERED** pursuant to 5 U.S.C. §706(2) that the Challenged Directives are **VACATED** and **SET ASIDE**.

IV. It is hereby **ORDERED** pursuant to 5 U.S.C. §706(2) that any notices of termination transmitted to Plaintiffs from January 20, 2025, to the present, that invoke the Agency-Priorities Regulation or that rely on any of the grounds for restricting NIH funding that are set forth in the Challenged Directives, whether said notices of termination were communicated by letter, by email, or in a revised notice of award (collectively, the "Priorities-Based Terminations") are **VACATED** and **SET ASIDE**. Defendants are **ORDERED** to immediately reinstate the awards subject to the Priorities-Based Terminations.

V. Defendants, their officers, agents, servants, employees, and attorneys, and all others in active concert or participation with those persons, are hereby **PERMANENTLY ENJOINED**

from implementing or giving effect in any way to the Challenged Directives with respect to Plaintiffs, including by:

a. terminating, freezing, pausing, or otherwise suspending (whether or not by means of a formal communication) any NIH notices of award issued to Plaintiffs on any of the grounds for restricting NIH funding that are set forth in the Challenged Directives;

b. terminating, freezing, pausing, or otherwise suspending (whether or not by means of a formal communication), on the basis of the Agency-Priorities Regulation, any notices of award issued to Plaintiffs, to the extent that the termination, freeze, pause, or suspension is based on agency priorities identified after the issuance of the notice of award for the award in question; and

c. deeming, classifying, or otherwise characterizing any funding for awards subject to Priorities-Based Terminations as unused, expired, "unobligated" or "deobligated" funds such that they may revert to the U.S. Treasury at the end of the period of availability for those funds and/or the end of the fiscal year, as applicable.

VI. Defendants are hereby **ORDERED** that they must, in good faith, take such steps as are necessary to prevent explicit or implicit implementation of the Challenged Directives and/or Agency-Priorities Regulation and to reverse any implementation or enforcement of the Challenged Directives and/or Agency-Priorities Regulation that has occurred or is occurring, with respect to the Plaintiffs.

VII. Defendants are hereby **ORDERED** to:

a. provide a copy of this Order within 24 hours of entry to all Defendants, their employees, and anyone acting in concert with them, and to further notify them that the Challenged Directives are unlawful, null, and void; that the Agency-Priorities Regulation does not authorize the termination of an award based on priorities identified after the issuance of the notice of award for the award in question; and that the Challenged Directives and/or any interpretation of the Agency-Priorities Regulation that would authorize the termination of an award based on priorities identified after the issuance of the notice of award for the award in question, along with all prior formal and informal advice, opinions, or direction previously received or communicated to effectuate, implement or enforce the Challenged Directives or improper application of Agency-Priorities Regulation must be disregarded;

b. direct the recipients of this Order to comply with its terms;

c. notify all recipients that they are required to comply with this Order, under penalty of contempt; and

d. provide counsel for Plaintiffs with a copy of such communication(s), within seven (7) days of issuance of such communication(s);

VIII. Defendants are hereby **ORDERED** to file a status report with the Court within seven (7) days of entry of this order describing the steps taken to ensure compliance with this Order.

Dated: June ___, 2025

By the Court:

_____
HON. WILLIAM G. YOUNG
Judge of the United States

EXHIBIT A

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

EXHIBIT B

NIH 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)

EXHIBIT C

NIH 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 Michael S. Lauer -S Digitally signed by Michael S. Lauer -S Date: 2025.02.13 15:06:52 -05'00'
Deputy Director for Extramural Research, National Institutes of Health (NIH)

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

EXHIBIT D

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 pursuant to, among other authorities, 42 U.S.C. § 282(b) and 45 C.F.R. Part 75 (45 C.F.R. §§ 75.207, 75.210, 75.371–373),[1] the Director of NIH hereby directs:

> NIH personnel shall conduct an internal review of all contract solicitations and notices of funding opportunities; applications pending Type 1 and Type 2 awards; existing awards; cooperative agreements; and other transactions. Such review shall be aimed at ensuring NIH grants, contracts, cooperative agreements, and other transactions do not fund or support low-value and off-mission research activities or projects – including DEI and gender identity research activities and programs. NIH personnel should also ensure grants, contracts, cooperative agreements, and other transactions are free from fraud, abuse, and duplication, and are being implemented consistent with federal law.

This Directive shall be implemented by all relevant NIH 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

Matthew J. Memoli, M.D.
Acting Director 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.

EXHIBIT E

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

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.

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. 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,

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

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.

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  - **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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- Action 1: Funding IC must request an updated application/RPPR with the DEI language removed.
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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

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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.

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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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    - 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."
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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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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>
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Staff Guidance –Award Assessments for Alignment with Agency Priorities - March 2025

Background

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  - **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

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.
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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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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.

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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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    - 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.
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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

EXHIBIT F

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

Project SummaryThe COVID-19 pandemic and the c

PROJECT SUMMARYThis project seeks to use real-ti

PROJECT SUMMARYThe goal of the proposed resear

PROJECT SUMMARY/ABSTRACTDisparities continue
The All of Us Research Program has an explicit goal t

PROJECT SUMMARY/ABSTRACT An unprecedented r

PROJECT SUMMARY.Sexual and gender minority (SC

Project SummaryTransgender and other gender min
Project summary/abstractThe 2024 National LGBTQ
The All of Us Research Program has an explicit goal

Project SummaryBackground/Objective: Transgende

PROJECT SUMMARYNo changes being proposed.INT
Project SummaryThe goal of this study is to test the effic

Project SummarySexual and gender minorities (SGM

Project SummaryNearly half of sexual minority (SM)

The "Patient-Responsive Initiatives for Diverse Enga
Project SummaryCategorization is a fundamental as

ABSTRACTOne in two Black men who have sex with

PROJECT SUMMARYRacial ethnic and sexual and ge
Project Summary/AbstractThe Stanford Genomics D

Project SummaryThis proposal seeks continued sup
PROJECT SUMMARYTHIRD COAST CFAR DEi PROGF
PROJECT SUMMARYDiversity enhances creativity ar

Project SummaryThe scope of this study is to engag

The University at Buffalo (UB) NIMHD Center of Exce
Project Summary/AbstractBackground: Structural ra

Background: Black women represent the largest gro

Background: Black women represent the largest gro

Project SummaryStress is associated with HIV risk b

Project Summary Overdose deaths are exponentiall

AbstractTransgender and gender diverse adults (TGDAs)

PROJECT SUMMARY/ABSTRACTStructural racism ar

Project Summary/ AbstractSocial justice is the prim

Project SummaryBlack and Latinx gay and bisexual men

Project Summary/Abstract The goal of this R01 is to

PROJECT SUMMARY Inequities in health manifest as

PROJECT SUMMARY/ABSTRACTIt is estimated that r

Project SummaryBlack cisgender women (hereafter

PROJECT SUMMARY/ABSTRACTThere is evidence of

Sex differences in immunity are dynamic throughout the
PROJECT ABSTRACTHeadache has been one of the top th
Project SummaryThis project will elucidate the psycholo
Sex Hormones and Identity affect Nociceptive Expressio
PROJECT SUMMARYThis R01 proposal responds to N

This proposal will undertake preclinical studies to a

PROJECT ABSTRACTWounds have a sizable impact

The University of Georgia (UGA) proposes a renewal of P

Project Summary/Abstract Science is failing minorities i

ABSTRACTThe vision of the Utah Clinical & Translational

Project SummaryThe goal of this study is to test the

PROJECT SUMMARY/ABSTRACTSexual minorities (i.

Sex Hormones and Identity affect Nociceptive Expression (SHINE)
Unequal Parenthoods: Population Perspectives on Gender Race and Sexual Minority Disparities in Family Stress and Health During Crises
Impact of Social Cohesion and Social Capital in PrEP Uptake and Adherence Among Transwomen of Color
Measures of structural stigmatization and discrimination for HIV research with Latine sexual and gender minorities
Exploring Stigma Social Support and Cancer Screenings among Sexual and Gender Diverse People Living with HIV in Georgia
PRIDEnet for the All of Us Research Program
Supportive and restrictive factors and mental health in LGBT adolescent and young adult populations
Project SMART: Social Media Anti-vaping Messages to Reduce ENDS Use Among Sexual and Gender Minority Teens
Development and Pilot Evaluation of an Online Mentoring Program to Prevent Adversities Among Trans and Other Gender Minority Youth
National LGBT Health Conference 2024
PRIDEnet for the All of Us Research Program
Development of a School-Based Prevention Intervention to Promote Adolescent Mental Health Equity
Effects of Social Networks and Policy Context on Health among Older Sexual and Gender Minorities in the US South
Efficacy of a Multi-level School Intervention for LGBTQ Youth

Training Program in Translational Science HIV and Sexual and Gender Minority Health
An Innovative Prospective Model to Understand Risk and Protective Factors for Sexual Assault Experiences and Outcomes Among Sexual Minority Men
PRIDE-CARES Center: Patient-Responsive Initiatives for Diverse Engagement - LGBTQ+
Community Action in Research to Eliminate Substance Use Disorder
Views of Gender in Adolescence
Intersectional Discrimination and Sexual Health Among Young Black Men who Have Sex with Men: A Mixed Methods Study
SILOS: Structural Inequities across Layers Of Social-Context as Drivers of HIV and Substance Use
Genomics Diversity Summer Program (GDSP) at Stanford
A Longitudinal Examination of Mechanisms Underlying Intersectional Health Disparities in the United States
Partnering and Programming for a BIPOC SGM Pathway to HIV Research
Faculty Initiative for Improved Recruitment Retention and Experience (FIIRRE)

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
Igniting Hope in Buffalo New York communities: Training the Next Generation of Health Equity Researchers
Developing Modules to Address Microaggressions and Discriminatory Behaviors
Monitoring Microaggressions and Adversities to Generate Interventions for Change (MMAGIC) for Black Women Living with HIV
Monitoring Microaggressions and Adversities to Generate Interventions for Change (MMAGIC) for Black Women Living with HIV
Health disparities stress pathways and stress-related comorbidities among MSM living with HIV
Exploring Historical Trauma Racial Discrimination PTSD and Substance Use Among Black Young Adults
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
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
Securing Health Equity: Philosophical Foundations for Equality and Social Justice in Public Health and Health Care
Theoretically Informed Behavioral Intervention to Enhance QOL and Prevent HIV-related Comorbidities in Ethnic and Racial Sexual Minority Men
Identifying multilevel facilitators of care outcomes among Positive Deviants to design an intervention for Black sexual minority men living with HIV
Multilevel Racism & Discrimination and PrEP Outcomes Among Black SMM in the Southeastern U.S.

Understanding the effects of cross-sex hormone therapy on vaginal mucosal immunity
A Multi-Level Trauma-Informed Approach to Increase HIV Pre-exposure Prophylaxis Initiation among Black Women

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
Understanding transgender women's immune and behavioral responses to seasonal COVID-19 vaccines to improve their uptake
Effect of pubertal hormones on Headache in Transmasculine Adolescents
The psychological underpinnings of gender disparities in adolescent mental health
Sex Hormones and Identity affect Nociceptive Expression (SHINE)
Androgen effects on the reproductive neuroendocrine axis

Gender-Affirming Testosterone Therapy on Breast Cancer Risk and Treatment Outcomes
Molecular Mechanisms of Hormone-Mediated Sex Differences in Wound Healing
PREP at University of Georgia
Culturally-focused HIV Advancements through the Next Generation for Equity (CHANGE) Training Program
CTSA UM1 Program at University of Utah
Efficacy of a Multi-level School Intervention for LGBTQ Youth
The Socioecology of Sexual Minority Stigma: Data Harmonization to Address Confounding Bias and Investigate Cross-Level MentalHealth Effects

3R01NR019417-03S1	UNIVERSITY OF ALABAMA AT BIRMINGHAM	$50,000
5U01HD108779-04	UNIVERSITY OF MINNESOTA	$225,000
5R01MD013554-05	COLUMBIA UNIVERSITY HEALTH SCIENCES	$507,062
1R01MD020284-01	DREXEL UNIVERSITY	$812,946
3R01NR020154-04S1	EMORY UNIVERSITY	$87,833
4OT2OD025276-03	STANFORD UNIVERSITY	$1,444,263
1R61HD117134-01	HARVARD PILGRIM HEALTH CARE, INC.	$838,837
5R01DA054236-04	UNIVERSITY OF PENNSYLVANIA	$681,337
5R21MD018509-02	UNIVERSITY OF NEBRASKA LINCOLN	$236,949
1R13MH138043-01	EMORY UNIVERSITY	$20,000
4OT2OD025276-03	STANFORD UNIVERSITY	$1,444,263
1R34MH136018-01A1	BOSTON COLLEGE	$139,551
3R01AG063771-05S1	VANDERBILT UNIVERSITY	$99,998
5R01MD016082-04	WASHINGTON UNIVERSITY	$565,297
5T32MH130325-03	NORTHWESTERN UNIVERSITY AT CHICAGO	$497,664
5R01MD016384-03	UNIVERSITY OF NEBRASKA LINCOLN	$767,135
1R24DA061190-01	UNIVERSITY OF SOUTH CAROLINA AT COLUMBIA	$503,095
3R01HD092347-08S1	PRINCETON UNIVERSITY	$97,554
1F31MH138075-01	DUKE UNIVERSITY	$42,014
1R01DA061247-01	NORTHWESTERN UNIVERSITY AT CHICAGO	$777,568
5R25HG010857-05	STANFORD UNIVERSITY	$285,283
2R01HD094081-06A1	UNIVERSITY OF MINNESOTA	$672,168
3P30AI117943-10S1	NORTHWESTERN UNIVERSITY AT CHICAGO	
5U54CA272171-03	UNIVERSITY OF SOUTH CAROLINA AT COLUMBIA	$4,386,670

5R01NR020583-03	COLUMBIA UNIVERSITY HEALTH SCIENCES	$798,648
1P50MD019473-01	STATE UNIVERSITY OF NEW YORK AT BUFFALO	
5R25GM149980-02	CHILDREN'S HOSP OF PHILADELPHIA	$91,048
3R01MH121194-04S1	UNIVERSITY OF MIAMI CORAL GABLES	$72,588
5R01MH121194-04	UNIVERSITY OF MIAMI CORAL GABLES	$642,346
5R01MD013495-05	JOHNS HOPKINS UNIVERSITY	$1,285,395
1R36DA058830-01A1	NEW SCHOOL UNIVERSITY	$53,501
5R01AA030275-02	GEORGIA STATE UNIVERSITY	$501,825
5R01MD017509-03	UNIV OF ARKANSAS FOR MED SCIS	$760,276
1G13LM014426-01	UNIVERSITY OF WASHINGTON	$47,535
1R01MD019956-01	YALE UNIVERSITY	$1,054,907
1R01NR021691-01A1	GEORGE WASHINGTON UNIVERSITY	$676,457
5R01MH130166-03	US HELPING US, PEOPLE INTO LIVING, INC.	$601,194
5R21AI178913-02	BOSTON MEDICAL CENTER	$222,500
5R01MD019178-02	JOHNS HOPKINS UNIVERSITY	$1,105,281
1F31MD019521-01A1	UNIVERSITY OF HOUSTON	$36,978
1R21AI183544-01A1 Already terminated 3/	NEW YORK BLOOD CENTER	$267,121
5K23NS130143-02	UNIVERSITY OF COLORADO DENVER	$224,924
5F32MH135634-02	PRINCETON UNIVERSITY	$73,828
5R01NR019417-03	UNIVERSITY OF ALABAMA AT BIRMINGHAM	$473,872
5R01HD111650-02 already terminated	UNIVERSITY OF CALIFORNIA, SAN DIEGO	$581,671

1R56CA284564-01	BETH ISRAEL DEACONESS MEDICAL CENTER	$299,940
1R35GM157032-01	BRIGHAM AND WOMEN'S HOSPITAL	$442,444
2R25GM109435-10	UNIVERSITY OF GEORGIA	$343,158
5T32MH126772-04	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	$286,511
5UM1TR004409-02	UNIVERSITY OF UTAH	$5,424,809
5R01MD016082-04	WASHINGTON UNIVERSITY	$565,297
5R01MH133821-02	SAN DIEGO STATE UNIVERSITY	$447,178
		$32,563,719

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.

EXHIBIT G

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

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

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

[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.

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.

- 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

- 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.

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 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.

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.

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

---

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

Appendix 5 – Notice of Funding Opportunity (NOFO) Guidance

[pending]

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.

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.

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).

- 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

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

[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.

- **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

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.

- 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**

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.

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.

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.**

2: OD **Type 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.

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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

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.**

- **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.

- 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.

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.

Health Disparities: Pending.

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.

1

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, M.D., Acting Secretary

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.

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."

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

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

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).

- **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).

	○ 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.

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

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.

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.

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.

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.

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

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).

- 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

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

[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.

- **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

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.

- 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**

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.

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.

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.**

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.

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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

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.**

- **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.

- 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:

- **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.

Health Disparities: Pending.

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.

1

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, M.D., Acting Secretary

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.

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."

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

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

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).

- **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).

	○ 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.

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

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.

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.

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.

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.

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

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).

- 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

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

[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.

- **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

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.

- 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**

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.

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.

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.**

2: OD **Type 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.

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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

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.**

- **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.

- 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.

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.

Health Disparities: Pending.

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.**

1

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, M.D., Acting Secretary

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.

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."

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

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

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).

- **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).

	○ 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.

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

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.

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.

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.

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.

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

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).

- 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

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

[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.

- **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

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.

- 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**

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.

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.

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.**

2: OD **Type 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.

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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

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.**

- **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.

- 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:

- **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.

Health Disparities: Pending.

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.**

1

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, M.D., Acting Secretary

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.

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."

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

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

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).

- **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).

	○ 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.

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

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.

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.

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.

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.

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

EXHIBIT H

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

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

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

[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.

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.

- 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

- 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.

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 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.

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.

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

---

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

Appendix 5 – Notice of Funding Opportunity (NOFO) Guidance

[pending]

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.

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.

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED APRIL 2024-SEPTEMBER 2024 (TO BE DELETED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] 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) (2024). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], 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. 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. [INSERT EXPLANATION—EXAMPLES BELOW

- 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

[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.

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.].

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 [INSERT] 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 [the NIH Director or his designee] 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, [the NIH Director or his designee] 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,

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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).

[insert sig block]

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED DECEMBER 2022-MARCH 2024 (TO BE DELTED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2022 National Institutes of Health ("NIH") Grants Policy Statement,[13] and 2 C.F.R. § 200.340(a)(2) (2023). This letter constitutes a notice of termination.[14]

The 2022 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations generally should be determined by reference to the law in effect when the grants were made."[15]

The 2022 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."[16] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[17] 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. 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. [INSERT EXPLANATION—EXAMPLES BELOW

- 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

[13] https://grants.nih.gov/grants/policy/nihgps/nihgps_2022.pdf.
[14] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[15] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[16] 2022 Policy Statement at IIA-1.
[17] *Id.* at IIA-153.

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.].

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,"[18] no corrective action is possible here. The premise of Project Number [INSERT] 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.[19] 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*.[20]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[21] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[22]

You must submit a request for such review to [the NIH Director or his designee] 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, [the NIH Director or his designee] may grant an extension of time.[23]

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.[24]

Sincerely,

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[18] 2022 Policy Statement at IIA-154.
[19] *See* 2 C.F.R. § 200.343 (2023).
[20] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[21] *See* 45 C.F.R. § 75.374.
[22] See 42 C.F.R. Part 50, Subpart D.
[23] *Id.* § 50.406(a).
[24] *Id.* § 50.406(b).

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PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED DECEMBER 2021-NOVEMBER 2022 (TO BE DELETED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2021 National Institutes of Health ("NIH") Grants Policy Statement,[25] and 2 C.F.R. § 200.340(a)(2) (2022). This letter constitutes a notice of termination.[26]

The 2021 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations generally should be determined by reference to the law in effect when the grants were made."[27]

The 2021 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."[28] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[29] 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. 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. [INSERT EXPLANATION—EXAMPLES BELOW

- 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

[25] https://grants.nih.gov/grants/policy/nihgps/nihgps_2021.pdf.
[26] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[27] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[28] 2022 Policy Statement at IIA-1.
[29] *Id.* at IIA-152.

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.].

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,"[30] no corrective action is possible here. The premise of Project Number [INSERT] 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.[31] 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*.[32]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[33] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[34]

You must submit a request for such review to [the NIH Director or his designee] 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, [the NIH Director or his designee] may grant an extension of time.[35]

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.[36]

Sincerely,

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[30] 2021 Policy Statement at IIA-154.
[31] *See* 2 C.F.R. § 200.343 (2022).
[32] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[33] *See* 45 C.F.R. § 75.374.
[34] See 42 C.F.R. Part 50, Subpart D.
[35] *Id.* § 50.406(a).
[36] *Id.* § 50.406(b).

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

[insert sig block]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

March 7, 2025

President Katrina Armstrong
The Trustees of Columbia University in the City of New York
202 Low Library
535 W. 116 St.
New York, NY 10027

Dear President Armstrong:

Funding for Project Number [INSERT] 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) (2024). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], 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. 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.

NIH is responsible for ensuring that its limited resources are appropriately allocated. NIH policy is that grant dollars should support institutions that foster safe, equal, and healthy working and learning conditions conducive to high-quality research and free inquiry—and should not subsidize institutions that are not built on American values of free speech, mutual respect, and open debate.[6] In this vein, NIH is aware of recent events at Columbia University involving antisemitic action that suggest the institution has a disturbing lack of concern for the safety and wellbeing of Jewish students. Columbia's ongoing inaction in the face of repeated and severe harassment and targeting of Jewish students has ground day-to-day campus operations to a halt, deprived Jewish students of learning and research opportunities to which they are entitled, and brought shame upon the University and our nation as a whole. Supporting research in such an

[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, Section 4.

environment is plainly inconsistent with NIH's priorities and raison d'etre of funding and championing the very best American research and educational institutions.

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,"[7] no corrective action is possible here. The premise of Project Number [INSERT] 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.[8] 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*.[9]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[10] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[11]

You must submit a request for such review to Director 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.[12]

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.[13]

Sincerely,

Matthew J. Memoli, M.D., M.S.
Acting Director, NIH

[7] 2024 Policy Statement at IIA-156.
[8] *See* 2 C.F.R. § 200.343 (2024).
[9] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[10] *See* 45 C.F.R. § 75.374.
[11] See 42 C.F.R. Part 50, Subpart D.
[12] *Id.* § 50.406(a).
[13] *Id.* § 50.406(b).

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the [INSERT APPROPRIATE GPS CITATION TO MATCH AWARD DATE) 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 [insert correct GPS date that applies to the time the award was issued} Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], 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. 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 Project Number [INSERT] 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

[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.
[7] *See* 2 C.F.R. § 200.343 (2024).

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,

[insert sig block]

[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 I

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).

- 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

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

[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.

- **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

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.

- 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**

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.

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.

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.**

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

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.**

- **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.

- 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.

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.

Health Disparities: Pending.

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.**

1

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, M.D., Acting Secretary

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.

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."

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

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

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).

- **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).

	○ 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.

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

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.

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.

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.

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.

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

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.

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).

- 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

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

[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.

- **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

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.

- 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**

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.

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.

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.**

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

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.**

- **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.

- 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:

- **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.

Health Disparities: Pending.

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.

1

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 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.

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."

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

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

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).

- **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).

	○ 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.

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

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.

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.

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.

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.

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

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 -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf [IC Chief GMO Name], Chief Grants Management Officer, [IC Name]

Commented [KG4]: eRA: Can we remove is text if OD award?

Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[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)