

EXHIBIT 13

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

Category 1: The sole purpose of the project is related to an area that is no longer an NIH/HHS priority/authority (e.g., diversity supplements, diversity fellowships, or conference grant where the purpose of the meeting is diversity, etc. after the priorities memo is issued), and/or the application was received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority. **Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.**

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
 - Issue a revised award to end the award **at the end of the current budget period and** remove all outyears. A termination letter is not required.
 - Add the action to the master spreadsheet located at: [OD OPERA Grant Action Tracking](#) (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
 - Include the following term in the revised NOA:

Term of Award:

Effective with this Notice of Award, this project is terminated. **[Insert appropriate category from Appendix 3, verbatim]**. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, **[RECIPIENT NAME]** may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

This action aligns with [Termination - 2 C.F.R. § 200.340 \(a\)\(4\)](#). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to **[IC Director Name], Director, [IC Name]**.

- In this instance, **there is no hard funds restriction required**. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For second and third NCE's, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately end the grant project (use disapproved extension term below). If the non-NIH/HHS priority/authority research activities are ancillary to the project, approve the extension (use approved extension term below). Reminder – even if a grant project is in an NCE, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's may use the following term of award when approving/disapproving NCEs:
 - **Term of Award (approved extension):** The no-cost extension has been approved for this project to support an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, etc.] research or research training activities or programs. Any funds used to support such activities will result in a disallowance of costs, and funds will be recovered.
 - **Term of Award (disapproved extension):** The no cost extension request for this project has been denied. Please proceed with orderly phaseout of the project. NIH grant funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs.

Category 2: Project partially supports non-NIH/HHS priority/authority activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope). This means the non-NIH/HHS priority/authority activities are ancillary to the purpose of the project, in some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the Restriction Term of Award (see Action 2) in Section IV of the Notice of Award. No exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Note: Activities required to comply with [NIH inclusion policies](#) are not considered DEI activities.
- **Action 1:** Funding ICO must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file. The recipient/awardee cannot rebudget these funds, they must be recovered by the IC.
 - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
 - Sample language for requesting application updates from the AOR: It is the policy of NIH not to prioritize **[select one of the following: diversity, equity and inclusion (DEI) research programs, or other non-HHS/NIH priorities, or countries of concern]**. [Funding IC] has identified **[insert appropriate activity taken from the list above]** activities within section

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[XXXX] of your application. Please work with the PD/PI to update the application sections and adjust the budget as appropriate to remove all [insert appropriate activity] activities and submit these updates to the Program Official and Grants Management Specialist for review and approval.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See [eRA online help](#) for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.
- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, issue the award and include the following Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.

Term of Award (Approved 2/28/2025 – Refer to Appendix 4 for the approval from Dr. Memoli):

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa, etc.] research or related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes [select one of the following: diversity, equity and inclusion (DEI) research programs, vaccine hesitancy, climate change, etc.] or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

Please be advised that your organization, as part of the orderly phaseout process, will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award.

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

Term of Award: The diversity supplement associated with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific topics 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 ICOs 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. ICOs 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. ICOs 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. ICOs do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. **The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.**

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

[Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See [NOT-OD-25-104](#).

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
 - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": [State Department Countries of Particular Concern](#)
 - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: [State Sponsors of Terrorism](#)
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTs clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the [Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern](#) (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or [Office of Foreign Assets Control Sanctions List](#), as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - [appeal language](#).

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Type 1: HHS Departmental Authority Terminations.

- OPERA receives a list from the Director, NIH or designee.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
 - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
 - **Supplement Terminated Only:** If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
 - **Linked (or equivalent) Awards:** If one linked (or equivalent) award is terminated, the ICO is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the ICO must:
 - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
 - Change the budget and project period end dates to match the date of the termination letter.
 - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
 - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
 - Include the following Termination Term in the revised NOA:

This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

NIH is taking this action in accordance with [2 C.F.R. § 200.340](#) as implemented in [NIH GPS Section 8.5.2](#). This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

- Note: Appeals language must be included **prior to** October 1, 2025. After October 1, 2025, when HHS will fully adopt 2 CFR 200, per [2 CFR 200.340](#), termination actions taken based on agency priorities are not appealable. This is different from terminations based on noncompliance (administrative and programmatic).
- eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
 - Effective with the date of this revised Notice of Award, funding for Project Number **[insert grant number]** is hereby fully reinstated; therefore, the termination letter dated **[insert date]** is rescinded without conditions. Funds made available to **[insert institution name]** used to support **[insert the title of the project]** are no longer restricted and are available for use in accordance with the terms and conditions of the award.
 - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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2:
OD**SECTION IV – AI SPECIFIC AWARD CONDITIONS – [REDACTED]**Type
NIH

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. OPERA's Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
 - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be

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terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.

- Include the following Termination Term in the revised NOA:

This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
 - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
 - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
 - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
 - Change the budget and project period end dates to match the date of the termination letter.
 - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
 - Remove all future years from the project, where applicable.
 - Include the following Termination Term in the revised NOA:

This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
 - Change the budget and project period end dates to match the date of the termination letter.
 - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
 - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
 - Include the following Termination Term in the revised NOA:

This award is bilaterally terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

Please be advised that your organization, as part of the orderly phaseout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in [Teams](#).

Impacts on the Biomedical Workforce:

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- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS [11.4.3.4](#) for instructions on submitting waiver requests.
- **Early-Stage Investigators (ESI):**
 - o 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.
 - o **Restoring ESI status:** Investigators lose their [ESI eligibility](#) when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See [Requesting an Extension](#) for instructions.
- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS [Section 12.3.7](#), which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS’s Secretarial Directive on DEI-Related Funding – February 10, 2025.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

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

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department’s compliance with Federal civil rights law as well as the Department’s policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

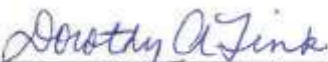
For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department’s authority to terminate for convenience contracts that are not “in the best interests of the Government,” see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.

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This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.


Dorothy A. Fink, M.D., Acting Secretary

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Appendix 2 – Guidance for staff to use on specific programs, awards, supplements.

- **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
- **Supplement Terminated Only:** If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated.
- **Linked (or equivalent) Awards:** If one linked award is terminated, the ICO is only required to terminate the specific award noted in the letter. The is should review and determine whether terminating that ward will have a structural impact on the scientific outcome originally intended by the ICO and act as appropriate on the remaining awards.
- **Diversity Tables** – Ignore and issue the grant using the term provided above.
- **Diversity Plans** – Ignore and issue the award using the term provided above.

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Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

- China: “Bolstering Chinese universities does not enhance the American people’s quality of life or improve America’s position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America’s foreign-policy objectives.”
- DEI: “Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion (“DEI”) studies are often used to support unlawful discrimination on the basis of race and other protected characteristics ICO’s, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.”
- Gender-Affirming Care: “Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.” **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- Vaccine Hesitancy: “It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.”
- COVID (to be used for HHS/NIH OD directed terminations only): “The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.” **Note: ICO’s may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO’s conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: “Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change.”
- Influencing Public Opinion: “This project is terminated because it does not effectuate the NIH/HHS’ priorities; specifically, research related to attempts to influence the public’s opinion.”

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Appendix 4 – Approved Term – Use for all Category 2 awards, i.e., renegotiated aims and associated budgets. Approval embedded below. ICO’s should use this term in the IC specific award conditions.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

From: [Memoli, Matthew \(NIH/OD\) \[E\]](#)
To: [Bundesen, Liza \(NIH/OD\) \[E\]](#)
Cc: [Bulls, Michelle G. \(NIH/OD\) \[E\]](#); [Lankford, David \(NIH/OD\) \[E\]](#); [Butler, Benjamin \(NIH/OD\) \[E\]](#); [Jacobs, Anna \(NIH/OD\) \[E\]](#); [Burklow, John \(NIH/OD\) \[E\]](#)
Subject: Re: Clean Version of DEI Restriction Term - Final
Date: Friday, February 28, 2025 2:54:19 PM

approved

Matt

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From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs, Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
 Liza

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals• **Prioritization of NOFOs**

Owner	Action
ICO	- Sends a priority list of upcoming NOFOs in two categories: - those that already have Concept Clearance (Option A)¹. - 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 <i>Forecast Template</i>. - Click “Save”. - Go to <i>Content</i> 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 <i>Description</i> section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. - Save record and notify the Guide when the forecast is ready for leadership approval (see below). - Sends email to the Guide mailbox when ready for leadership approval - NIH Guide (NIH/OD) nihguide@OD.NIH.GOV - Subject: NOITP ###-##-##-###- [IC Name] – [Desired Clearance Date] - Note: the number is important because of the variety of draft versions in FOAM. - Plan to implement FOAM task in future to remove dependence on email.

¹ For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are not approved.
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of approvals and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to “published” in FOAM once the content has been fully approved. • Notifies OPERA of the status via email.
OPERA	• Sends Forecast report to HHS². • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a “compare documents” of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. Note: FOAM has a compare documents feature.

² Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH’s NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.
--	---

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If no changes to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) [nihguide@OD.NIH.GOV](mailto:.nihguide@OD.NIH.GOV).

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Appendix 6 – Frequently Asked Questions

- 1. When reviewing applications for activities that are no longer an NIH/HHS priority/authority, should ICO's review the content of Other Support submissions?**

Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICO's do not need to review Other Support for alignment with NIH/HHS priorities/authority.

- 2. For phased awards where the second phase (i.e., Type 4) will not be awarded due to NIH/HHS priority/authority, how should the ICO notify the recipient that the Type 4 will not be issued?**

In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

- 3. When revising awards to terminate a project, how should the ICO respond to red bars in SEAR?**

The ICO should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICO's can clear the SEAR flag with a comment that the project is being terminated.

- 4. If a project is terminated on an HHS list or a Type 5 is withheld because the project is no longer an NIH/HHS priority/authority, can the ICO issue a subsequent Type 2 award?**

No. If a project has been terminated due to agency priorities, it is no longer eligible for a renewal award.

- 5. For recipients of K awards that are terminated due to NIH/HHS priority/authority, will eligibility requirements be modified to allow the individual to apply for another K award?**

Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

- 6. If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See [Requesting an Extension](#) for instructions.

- 7. When ICO's issue revised NOAs to terminate awards, do they have to use the exact language provided by HHS in the termination term?**

Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

- 8. Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?

Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?

Yes. All monetary revisions are subject to this guidance.

11. Can ICO's approve requests from recipients to modify the project title?

Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. When ICO's receive questions from recipients regarding HHS terminations, what should they do?

ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?

An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?

For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with [2 CFR 200.340\(a\)\(4\)](#). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. When will the Final RPPR become available for recipients to prepare and submit?

The F-RPPR link will open once the project period has ended.

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16. Can recipients draw down funds after the stated termination date?

For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?

The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. Will recipients have the standard 120-day period following the termination date to submit closeout reports?

Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?

Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?

When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?

Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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- 22. Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.**

The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

- 23. If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?**

No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

- 24. For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?**

Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

- 25. For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?**

Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

- 26. If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?**

No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

- 27. If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?**

Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

- 28. For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.**

In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2024 National Institutes of Health (“NIH”) [Grants Policy Statement](#), and 2 C.F.R. § [200.340\(a\)\(4\)](#). This letter serves as a termination notice.

The 2024 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and “obligations for federal grants are generally determined by the laws, regulations, and terms in effect at the time the grant was awarded, as outlined in the Notice of Award (NOA) or grant agreement”. This “includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.”

According to the Policy Statement, “NIH may ... terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.” At the time your grant was issued, 2 C.F.R. § 200.340(a)(4) permitted termination “[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.”

This project no longer effectuates agency priorities. [insert termination category language (e.g., DEI) verbatim]. Therefore, there is no modification of the project that would align with agency priorities.

Although “NIH [generally will suspend](#) (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,” no corrective action is possible here.

Costs resulting from financial obligations incurred after termination are not allowable. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by [2 C.F.R. §200.344](#). However, due to the immediate termination of this project, NIH may require a shortened timeframe to submit closeout reports. Details will be provided in the revised NOA issued by the Grants Management Official.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO’s termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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.