

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where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority.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.

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.

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- 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