

EXHIBIT 18

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

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 The August 15, 2025, Priorities Statement superseded the February 21, 2025, statement of the Acting NIH Director, “Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards.” The February 21, 2025, statement is no longer in effect.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 The prior Staff Guidance is no longer in effect.

Applicability

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

Background

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

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

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

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

Procedures

Project Assessment

As projects approach the next Type 5 or a Type 1 or 2 is moving to To Be Paid status, ICOs must assess each project for alignment with NIH priorities.

ICOs should review awards that are nearing the end of the project period and may be preparing to initiate no-cost extensions to determine if the extension should be allowed.

ICOs are responsible for their respective portfolio reviews.

First, the ICO must use the computational text analysis tool to evaluate the award. This tool is currently maintained for ICO use by NIGMS and looks for terms that have been found to be associated with grants that are not aligned with the NIH's priorities.

If the text analysis tool identifies any potential aspects of the project that do not align with NIH priorities, the appropriate ICO staff must manually evaluate the award using the August 15, 2025 [NIH Director's Statement of NIH Priorities](#) and its addenda, if any. The determinations must be linked to the appropriate priority and the ICO must document the specific areas of the project that do not align with the NIH's priorities in their determination. A few clarifying points to note are:

- Pay particular attention to the use in grants of poorly defined, non-scientific or subjective terms and variables, as defined in the August 15, 2025 [NIH Director's Statement of NIH Priorities](#) and its addenda, to frame or justify the research. Frequent examples are "health equity" and "structural racism." If these can be replaced with well-defined, scientific concepts that have objective and measurable variables, then the grant can likely be renegotiated to focus on those instead. For example, framing around "health equity" might be refocused to emphasize studying and ameliorating a particular health disparity. In some cases, however, the entire premise of the grant relies on subjective or poorly defined, non-scientific terms, in which case it might not be possible to renegotiate it.
- Health disparities research is within the NIH's priorities as long as it is scientifically justified and the interventions or potential interventions relate to areas that can be directly influenced by healthcare or biomedical science. Examples of areas that would not be directly influenced by healthcare or biomedical science include (but are not limited to) poverty, employment, and immigration.
- NIH-funded research can focus on or include specific populations - such as racial or SG minorities - if it is scientifically justified. For example, the disease/condition could be more prevalent in a certain group, or that group is not currently sufficiently represented in studies of a potential therapeutic to make conclusions about its efficacy or side effects in the group.
 - Specific groups included in research studies should be described using clearly defined, standardized terms. For racial and ethnic groups, OMB's reporting categories (SPD 15) should be used: <https://www.census.gov/newsroom/blogs/random-samplings/2024/04/updates-race-ethnicity-standards.html>. Terms such as LatinX

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

- A clinical study that says it plans to increase the diversity of its patient base is within the NIH's priorities as long as the need for increased patient diversity is scientifically justified.
- Grants intended to increase workforce diversity by granting preferential treatment to individuals based on protected characteristics such as race or ethnicity are not consistent with the NIH's priorities. If they are focused on trainees early in their careers (e.g., undergraduates) they can often be renegotiated because their goals are not tailored to specific groups. Programs to promote diversity in the workforce at later careers stages, such as faculty members, are often harder to renegotiate particularly if they are tailored towards specific groups (e.g., underrepresented populations). Limiting program eligibility or giving preferential eligibility to members of specific groups based on protected statuses such as race, ethnicity or sex is not consistent with the NIH's priorities and is likely to be legally problematic.
 - Grants that are aimed at building research capacity at certain types of institutions, states or regions are within the NIH's priorities if there is a clear need and justification. Examples include resource-limited institutions and IDeA states.
 - Grants supporting research involving federally recognized American Indian or Alaska Native Tribes are within the NIH's priorities.
- Direct foreign awards must be strongly justified in terms of providing unusual talent, resources, populations, or environmental conditions that are not readily available in the United States and must provide the opportunity to significantly advance health sciences in the U.S.
- Please keep an eye out for grants that are overtly political in nature – for instance, take a clear political side rather than adopting a neutral, scientific approach to answering a question – and for grants that contain work that could be construed as lobbying. These grants could violate the NIH's Terms and Conditions of Award:
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.5_lobbying_-_appropriation_prohibition.htm?Highlight=lobbying.
- The ICO must ensure the award program aligns with the granting authorities (can consult OPERA as needed). See Item 13 on page one of the Notice of Award. The most common granting authorities that are used include but are not limited to:
 - Research, Career Development, Conference Grants, Research Education Awards: 42 USC 241; 42 CFR 52
 - Training and Fellowship: 42 USC 288; 42 CFR 66
 - NIEHS Hazardous Materials Training: 42 USC 9660a; 42 CFR 65
 - International Research Training Grants: 42 U.S.C. 287b; 42 C.F.R. Part 63a
- Internal approval processes may be managed at the ICO level, as long as all decisions are fully documented in the grant file.

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

Renegotiation

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

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

Termination

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

Appendix 1– Information to Provide OPERA for a Decision Analysis

1. IC Designated Official
2. Award Number and Title
3. Cite relevant granting authority (e.g., 42 USC 241and 284 as implemented under 42 CFR Part 52).
4. Insert language from granting authority that outlines the purpose of the award program. Select one of the following options, as applicable. If ICOs identify any activities not covered here, contact OPERA.:

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

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

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

9. Quote the relevant language from the August 15, 2025, priority statement that relates to the nonalignment identified under the award
10. Describe how the award is not in alignment with agency priorities for NIH. Be as specific as possible. If there are aspects of the award that might weigh in favor of not terminating it (e.g., an aspect might support advancement of a different agency priority), address how terminating the award overall outweighs those aspects.
11. Describe why renegotiation is not possible.
12. Address reliance interests of recipients, beneficiaries of the award program and/or award, and the public generally. Reliance interests include reasonable actions the grantees took based on their expectations for continuation of the award, such as hiring or student recruitment. Also address potential impacts on public health and subrecipients.