EXHIBIT 5

NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NIH National Institutes of Health

APRIL 2024

specified or NIH will administratively withdraw the application and it will not be reviewed or considered for funding.

The PD/PI must include a cover letter with the application identifying the PO contacted and the IC that has agreed to accept assignment of the application. CSR will accept such applications for review only if an IC has agreed to accept the application for consideration and the applicant submits with its application a cover letter to that effect with the name of the authorizing program staff member and IC affiliation (see The Peer Review Process). An application subject to this policy that does not include the required information in the cover letter will be administratively withdrawn and will not be reviewed or considered for funding.

2.3.7.3 Resubmission of Unfunded RFA Applications

This policy applies to all activity codes that might be solicited via an RFA and to instances where there is a change in activity code. Unless a particular NOFO states that resubmissions from an RFA may be submitted, unfunded applications should be submitted as **new** applications if the grant applications fall into the following categories:

1. Applications that were originally submitted in response to an RFA and now submitted as an investigator-initiated application.
2. Applications that were originally submitted as investigator-initiated applications and subsequently submitted in response to an RFA.
3. Applications that were originally submitted using one grant activity code and subsequently submitted using a different grant activity code (for example, an application that was originally an R01 and is now submitted as an R21).

The new application must be submitted on the scheduled due dates for new applications and follow all instructions that apply to new applications. Do not include an Introduction describing the changes and improvements made; do not mark text to indicate the changes and do not mention prior review anywhere in the application (including the cover letter). In these cases the reviewers will not be provided with the previous summary statement.

2.3.7.4 Resubmission of an Unfunded Application

An unfunded competing application (A0) may be resubmitted for future funding opportunities. These applications are referred to as a resubmission application (A1). NIH will only accept a single resubmission (A1) application. NIH will accept a new (A0) application following an unsuccessful resubmission (A1) application or a prior A0 application. The subsequent new application need not demonstrate substantial changes in scientific direction compared to previously reviewed submissions, and must not contain an introduction to respond to the critiques from the previous review. NIH's policy for accepting overlapping applications remains in effect: NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that NIH will not review:

1. a new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
2. a resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
3. an application that has substantial overlap with another application pending appeal of initial peer review (see Section 2.3.9.4 below)

NIH policy allows a 37 month window for one resubmission (A1) following the submission of a new, renewal, or revision application (A0 application). The initial submission of a new, renewal or revision

application constitutes the starting point for the 37 month policy. After 37 months, NIH views a submission as a new application, regardless of whether an unsuccessful resubmission (A1) was submitted during the 37 month period.

Submission to a different NOFO under review at the same time is not sufficient to make an application new. (There are exceptions for applications following an RFA or changing activity code. See Resubmission of Unfunded RFA Applications above). The new application must be submitted on the scheduled due dates for new applications. It must not include an Introduction describing the changes and improvements made; and the text must not be marked to indicate the changes.

2.3.7.5 New Investigators and Early Stage Investigators

The NIH is committed to identifying and attracting new biomedical researchers and will continue to explore novel ways to encourage early transition to independence. NIH has implemented a number of policies specific to New Investigators, and in particular the category of New Investigator called Early Stage Investigator.

New Investigator. In general, a PD/PI is considered a New Investigator if they have not previously competed successfully as PD/PI for a substantial NIH independent research award. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. See definitions section for additional information and references.

Early Stage Investigator (ESI). An ESI is a New Investigator who has completed their terminal research degree or end of post-graduate clinical training (i.e., completing medical residency, whichever is later, within the past 10 years at the time of application submission and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award. Extensions of the end of ESI eligibility date may be requested following the procedures documented on the Early Stage Investigator Extensions page on the NIH Grants & Funding website. Please note an investigator will retain their ESI status if they receive smaller research grants, training, infrastructure, and career awards appearing on this list.

The NIH intends to support New Investigators at success rates comparable to those for established investigators submitting new applications. ESIs should comprise a majority of the New Investigators supported. Where possible, New Investigator applications will be clustered during review. The applications will be given special consideration during peer review and at the time of funding. Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator.

NIH New Investigator policies are limited to applications for traditional research project grant (R01) support. Accordingly, NIH strongly encourages New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding. To determine New Investigator and ESI status, NIH relies on the data entered by the individual in their eRA Commons Profile, therefore it is important that PD/PIs verify the accuracy of their personal profiles. Particularly key for ESIs are the terminal research degree and end date of residency data fields. ESI status and end of eligibility date also appear in the eRA Commons profile for the individual.

2.3.7.6 Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance

The applicant organization is required to secure and retain a unique signature and dated assurance from the PD/PI for each submitted application, prior to submitting an application to the NIH. This assurance must be available to the NIH or other authorized DHHS or Federal officials upon request. Such an assurance must include at least the following certifications: 1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; 2) that any false, fictitious, or

2.3.12 Protecting Sensitive Data and Information Used in Research

Recipients of NIH funds have a vital responsibility to protect sensitive and confidential data as part of proper stewardship of federally funded research, and take all reasonable and appropriate actions to prevent the inadvertent disclosure, release or loss of sensitive personal information. NIH advises that personally identifiable, sensitive, and confidential information about NIH-supported research or research participants not be housed on portable electronic devices. If portable electronic devices must be used, they should be encrypted to safeguard data and information. These devices include laptops, tablets, mobile devices, CDs, disc drives, flash drives, etc. Researchers and institutions also should limit access to personally identifiable information through proper access controls such as password protection and other means. Research data should be transmitted only when the security of the recipient's systems is known and is satisfactory to the transmitter. See also Public Policy Requirements and Objectives—Federal Information Security Management Act.

2.4 THE PEER REVIEW PROCESS

NIH policy is intended to ensure that applications for funding submitted to NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias. Competing applications for NIH grants and cooperative agreements, including renewals and revisions, are subject to peer review as required by sections 406 and 492 of the PHS Act, as amended by the NIH Reform Act of 2006 and 21st Century Cures Act. The peer review system used by NIH, often referred to as the "dual review system," is based on two sequential levels of review for each application—initial review by an IRG or SRG, and a second level of review for scientific merit by the IC National Advisory Council/Board.

The NIH peer review process has evolved over the years to accommodate increasingly collaborative and multi-disciplinary research, changes in workload, resource constraints, and recommendations of various scientific and professional groups. However, the underlying basis for the system—to provide a fair and objective review process in the overall interest of science—has not changed. Information concerning NIH's peer review process may be found at NIH's web site or Peer Review Policies and Practices on the NIH Grants & Funding web site.

2.4.1 Initial Review

2.4.1.1 Responsibilities

The DRR in the CSR receives all competing grant applications submitted to NIH, whether the peer review will be conducted by CSR or by an IC. The primary determining factors in whether CSR or an IC will be responsible for the peer review are the announcement type, the support mechanism, and/or the program. In general, CSR is responsible for the initial review of research project grant applications (including NIH Research Enhancement Award applications), Kirschstein-NRSA individual fellowship applications, and SBIR/STTR applications, while the ICs handle the initial review of applications that have Institute-specific features such as conference grant applications, applications resulting from RFAs, and program project and center grant applications. CSR also may review other types of applications at an IC's request.

When the IC is responsible for the initial review, CSR reviews the application for completeness and staff in the soliciting IC review the application for responsiveness to the RFA/PAR/PAS, if applicable. The scientific review office in that IC coordinates the initial technical review for scientific merit and prepares the summary statements.

CSR Referral Officers, who are senior health scientist administrators with both research and scientific review experience, assign each application to one or more ICs for potential funding and to an IRG or SRG for initial review of the scientific merit of the application. These assignments are made on the basis of the application's contents, the referral guidelines, and any written request by the applicant organization (accompanying the application) for a specific study section or IC assignment.

SRGs, including CSR study sections, are organized by scientific discipline or current research areas and are managed by health scientist administrators functioning as SROs. Generally, study sections are chartered groups composed of formally appointed members serving multiyear terms, to which the SRO often adds temporary members or other additional reviewers. Ad hoc SEPs are formed to review applications that cannot be reviewed by a standing review group or study section because they require special expertise or involve other special circumstances.

SRGs, whether study sections or SEPs, are primarily composed of non-federal scientists who have expertise in relevant scientific disciplines and are actively engaged in research. NIH's conflict-of-interest and confidentiality of information requirements for reviewers are intended to promote an unbiased review process by minimizing even the appearance of a conflict of interest and by restricting the use of privileged application information.

Applicants are notified by e-mail that their application has been received and that they can find information about the application's SRO, SRG, and IC assignments in eRA Commons. At this time, applicants may request reconsideration of the SRG and IC assignment. Applicants also are notified by e-mail to check eRA Commons for any change in the application's SRG or IC assignment, as well as a change in Council date. Once the assignment process is completed, the SRO, not the PO, is the primary contact for communication with the applicant until the summary statement is released. An applicant organization may withdraw an application from consideration at any time during the review process. A request to withdraw an application must be signed by the PD/PI and an AOR, and submitted to the SRO.

In preparation for the initial review, SROs review applications to determine whether they are complete and conform to administrative requirements. For each reviewable application, they then assign (from among the standing and temporary members) at least three reviewers to write a critique of the application, provide initial scores, and to be prepared to discuss the application in detail.

Following the initial review, the SRO prepares a summary statement for most applications reviewed. The summary statement includes the reviewers' written comments, and, for scored applications, a summary of the discussion, and an impact score. Summary statements are then simultaneously provided to the IC's program staff, Advisory Councils, the PD(s)/PI(s), and applicant institution's Authorized Organization Representative.

2.4.1.2 Overall Impact

The SRG assesses overall impact in the determination of scientific and technical merit; overall impact is defined based on the different types of applications. When considering applications for research grants and cooperative agreements, reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five scored review criteria, and additional review criteria (as applicable for the project proposed). All the criteria, weighted as appropriate for each application or as described in the NOFO, will be considered when assigning the overall impact score.

2.4.1.3 Scored Review Criteria

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, enhance health, and reduce illness and disability. For research grant applications, and most other types of applications, reviewers evaluate the overall impact to reflect their assessment of

the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, taking into account, among other pertinent factors: Significance, Investigator(s), Innovation, Approach, and Environment. These scored review criteria may not be applicable for some types of applications. When these criteria are not applicable, the NOFO will include the specific review criteria.

Reviewers will consider each of the five criteria below in the determination of scientific and technical merit, and determine a separate score for each. An application does not need to be strong in all categories to be evluated likely to have a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

The NOFO should be consulted for additional information describing each of the scored review criteria.

2.4.1.4 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- Diversity Plan (for Conference Grant Applications)
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan.
- Vertebrate Animals
- Biohazards
- Resubmission Applications
- Renewal Applications
- Revision Applications

The NOFO should be consulted for additional information describing each of the relevant additional review criteria.

2.4.1.5 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and Reviewers should not consider these items in providing an overall impact score.

- Provision of Family Care Facilities (for Conference Grant Applications)
- Applications from Foreign Organizations
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

The NOFO should be consulted for additional information describing each of the relevant additional review considerations.

Although the review criteria are intended for use primarily with investigator-initiated research project grant applications (e.g., R01 and P01), including those in response to PAs, to the extent reasonable, the criteria also will form the basis of the review of solicited applications and research related activities. However, for some activities (e.g., construction grants), the use of these criteria may not be feasible. Applications also may be reviewed against other pertinent factors as stated in NOFOs.

2.4.2 Appeals of Initial Scientific Review

To preserve and underscore the fairness of the NIH peer review process, NIH has established a peer review appeal system to provide applicants the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was procedurally flawed. The NIH policy for appeals of initial peer review does not apply to appeals of the technical evaluation of Research and Development contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT awards. In addition, NIH will not review a resubmission application when an appeal of initial peer review is pending on the original application. As stated in the Notice of Funding Opportunity, appeals of initial peer review outcome will not be accepted for applications in response to an RFA.

An appeal is a written communication from a Program Director/Principal Investigator (PD/PI) and/or applicant institution that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw or perceived flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence from the Authorized Organization Representative (AOR).

An applicant who is concerned about procedural aspects related to the completed initial peer review of their application first should consider the comments in the summary statement, and then should contact the appropriate NIH Program Official (PO). Following discussion of concerns with the PO, if the PD/PI and/or an official of the applicant organization wishes to appeal the outcome of the initial peer review process, an appeal letter must be submitted, either in hard copy or electronically, to the PO. The appeal letter must display concurrence from the AOR of the applicant organization for the application. Although the content of the appeal letter may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the letter directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and AOR concurrence to the PO. A communication from the PD/PI or official of the applicant organization (other than the AOR) only or with a “cc” to the AOR will not be accepted. The PO will send the PD/PI and/or institutional official, and AOR, an acknowledgement letter within 10 days of receipt of the appeal letter.

An appeal letter will be accepted only if the letter 1) describes the flaws in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers.
- Conflict of interest, as specified in regulation at 42 CFR Part 52h.5 “Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects”, on the part of one or more non-Federal peer reviewers.
- Lack of appropriate expertise within the SRG.

- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal letter, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

If review staff and program staff do not support the appeal, or do not agree on its merit, the PD/PI and/or an institutional official (not necessarily the AOR) may elect to withdraw the appeal letter. The request to withdraw an appeal letter must be submitted either in hard copy or electronically to the PO, and must display concurrence from the AOR of the applicant organization for the application. Although the content of the request may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the request directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and their concurrence to the PO. A communication from the PD/PI or institutional official (other than the AOR) only or with a "cc" to the AOR will not be accepted.

If review staff and program staff do not support the appeal, or do not agree on its merit, and the appeal letter is not withdrawn, the appeal letter will be made available to Council. The IC may not deny the PD/PI or applicant organization the opportunity to have an appeal letter made available to Council. Only two outcomes are possible following consideration of an appeal letter by Council:

- The Council may concur with the appeal, and recommend that the application be re-reviewed.
- The Council may concur with the SRG's recommendation and deny the appeal. Although factual errors or other issues may be evident, the Council may determine that these factors were unlikely to alter the final outcome of the SRG and deny the appeal. No action by the Council is equivalent to concurrence with the SRG's recommendation and denial of the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

The Executive Secretary for the Council will communicate the Council recommendation concerning an appeal to the PD/PI, AOR, and NIH staff with a need to know. If the appeal letter was received by the IC deadline, the PD/PI and AOR will receive a written explanation of the resolution no later than 30 calendar days after the Council meeting. If the appeal letter was received after the IC deadline, the Executive Secretary will provide, no more than 30 calendar days after the date when the appeal letter was received, a written explanation of the IC's plan for making the appeal available to Council.

If the Council recommended that the application be re-reviewed, the original application will be re-reviewed without additional materials or modifications. The application may be re-reviewed by the same or a different SRG, depending on the flaws in the original review process that led to the appeal. In most cases, the re-review will entail re-assignment to a subsequent review round and delay in the final funding decision. The outcome of the re-review is final and cannot be appealed again.

On occasion, and for specific circumstances, the NIH may suspend temporarily the policy and process for handling appeals of NIH initial peer review. Such decisions will be announced in NIH Guide Notices and/or the relevant Notice of Funding Opportunity when they are issued in the NIH Guide for Grants and Contracts.

2.4.3 National Advisory Council or Board Review

Summary statements for those applications recommended for further consideration are presented to the assigned IC National Advisory Council or Board (hereafter "Council") for use in the second level of

review. Council members include senior scientists with broad experience and members of the public with general knowledge of, and interest in, the IC's mission. The Council reviews applications not only for scientific and technical merit, as judged by the SRG, but also for relevance to the IC's programs and priorities. The Council may concur with the SRG's recommendation, may decide not to recommend an application on the basis of program or policy considerations, or may recommend deferral of an application and refer it back to the SRG for re-review.

In addition, Council members will receive a list of competing applications that will be considered for funding from PD/PIs that meet the threshold for Special Council Review. These are investigators who currently receive $2 million or more in total costs (inclusive of direct and indirect) per year of NIH funding to support Research Project Grants. Council members will be asked to recommend consideration of funding for applications that afford a unique opportunity to advance research which is both highly promising and distinct from the other funded projects from the PD/PI. This does not represent a cap to NIH funding.

With very limited exception, an application may not be considered for funding unless it has received a favorable recommendation by both the SRG and the Council. For some applications (e.g., Kirschstein NRSA Fellowship applications) the second level of review is conducted by senior level IC staff.

2.4.4 Disposition of Applications

All incomplete applications, non-compliant applications, and applications determined to be non-responsive to NOFO requirements will not be reviewed. If the NOFO remains open with subsequent submission dates, the applicant may resubmit a corrected or complete version of an investigator-initiated application for consideration in the next review cycle. An application may resubmit one application may be submitted for an appropriate due date up to 37 months after the application due date of the initial application, provided the NOFO allows resubmission applications. Any application on the same topic proposed as a resubmission more than 37 months from the initial receipt date will not be accepted; it must be formatted and submitted as a new application.

For complete, compliant and responsive applications, following the initial scientific peer review, the summary statement will be available to the PD/PI and AORs of the applicant organization with the Signing Official (SO) user role in the eRA Commons. Applicants just receiving their summary statements should consult the NIH Next Steps page for detailed guidance. If an application does not result in funding, there may be an opportunity to respond to the reviewers' comments and resubmit the application, provided the NOFO allows resubmission applications. Applicants seeking advice beyond that available online may want to contact the NIH Program Officer listed at the top of the summary statement.

The IC Director or designee is the official who has the authority to make final award decisions from among those applications receiving a favorable initial review and Council recommendation. If an application has been recommended for further consideration but is not expected to be funded in the current cycle, the application may be held by NIH for one or more additional cycles and will compete with other applications submitted for that cycle. If an application is unsuccessful, the applicant may subsequently submit one revised version of the application (referred to as a resubmission) for review in a future cycle.

Some of the ICs publish paylines as part of their funding strategies to guide applicants on their likelihood of receiving funding. Application scores can only be compared against the payline for the fiscal year when the application will be considered for funding, which is not necessarily the year when it was submitted. At the beginning of fiscal years when the agency awaits an actual budget, there may be a delay of several months to determine paylines. If the application is assigned to an IC that does not announce a payline, the Program Officer listed at the top of the summary statement may be able to provide guidance on the likelihood of funding.

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The process leading to an award, including the business management review performed by the GMO, is described in Completing the Pre-Award Process below.

For unsuccessful applicants, the NIH will send a centralized, automated correspondence to the applicant organizations to notify them of NIH's intent not to fund the indicated applications.

The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any NIH or HHS official or board.

2.5 COMPLETING THE PRE-AWARD PROCESS

Following the peer review process, applications that an IC may fund are reviewed for a number of other considerations. These include, as applicable, alignment with NIH's funding principles, review of the project budget, assessment of the applicant's management systems, determination of applicant eligibility, and compliance with public policy requirements. The applicant may be asked to submit additional information (such as other support or verification of IACUC approval) or to undertake certain activities (such as negotiation of an F&A cost rate) in anticipation of an award. However, such requests by NIH do not guarantee that an award will be made. Following review of all applicable information, the IC will determine whether an award can be made, if specific award conditions are required, and what level of funding is appropriate.

Although these reviews and determinations occur before NIH makes a new award, recipients must continue to comply with eligibility and public policy requirements and maintain adequate management systems throughout the period of support. The pre-award process for non-competing continuation awards is a streamlined version of this process, including an assessment of progress (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports).

2.5.1 Just-in-Time Procedures

NIH uses Just-in-Time procedures for certain programs and award mechanisms (each NOFO will include specific guidance on the use). These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include other support information (both active and pending) for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement. Other program-specific information may also be requested using this procedure. (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.)

Applicants will be notified (primarily by e-mail) when Just-in-Time information is needed. This notification is not a Notice of Award nor should it be construed to be an indicator of possible funding. Applicants should only submit this information when requested. Information must be submitted electronically using the Just-in-Time feature in the eRA Commons. In some circumstances the GMO may ask for information in addition to the descriptions below, e.g., if the application involves hESCs and the applicant did not identify a hESC from the NIH Registry in the application.

The requirement for applicants to verify the accuracy and validity of all administrative, fiscal, and programmatic information extends to information submitted through the Just-in-Time process. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award. This includes items such as Other Support changes that could lead to budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PD/PI(s) or any Senior/Key Personnel; or any changes in the use or approval of vertebrate animals or

PART II: TERMS AND CONDITIONS OF NIH GRANT AWARDS

Subpart A: General

3 OVERVIEW OF TERMS AND CONDITIONS

Part II includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards. Subpart A (IIA) includes those terms and conditions that apply, in general, to NIH awards. Subpart B (IIB) either expands on IIA coverage or specifies additional or alternate terms and conditions for particular types of awards, recipients, or activities.

These terms and conditions are not intended to be all-inclusive. All awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts.

NIH recipients are responsible for complying with all requirements of the Federal award. NIH grants awards are based on the application submitted to, and approved by, the NIH and are subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in the NoA.
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts. This also includes any recent legislation.
- 2 CFR Part 200.
- The NoA including all terms and conditions cited on the document or attachments.

Notice of requirements not specified in the NIHGPS generally will be provided in the NoA, but such notice is not required for the award to be subject to the requirements of pertinent statutes and regulations. An individual award also may contain award-specific terms and conditions. For example, the GMO may include terms or conditions necessary to address concerns about an applicant's management systems.

Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Thus, the requirements of the NIHGPS apply in addition to governing statutory and regulatory requirements not cited herein, and award-specific terms apply in addition to the requirements of the NIHGPS.

This NIHGPS is an aid to the interpretation of statutory and regulatory requirements. These terms and conditions are intended to be compliant with governing statutes and the requirements of 2 CFR Part 200, as modified by previously approved waivers and deviations. However, in the case of a conflict, the statutes and regulations govern.

If there is a perceived conflict between or among these three categories of requirements—statutory and regulatory requirements, the terms and conditions in the NIHGPS, and award-specific terms and conditions—or if the recipient has other questions concerning award terms and conditions, the recipient

should request written clarification from the GMO. This may be done at any time; however, if the inclusion of the term or condition would cause the recipient not to accept the award or to be unable to comply, the question should be raised before funds are requested from the HHS payment system. By drawing funds from the HHS payment system, the recipient agrees to the terms and conditions of the award.

3.1 FEDERALWIDE STANDARD TERMS AND CONDITIONS FOR RESEARCH GRANTS

In order to create greater consistency in the administration of Federal research awards, all Federal research agencies now utilize a standard core set of administrative terms and conditions on research and research-related awards that are subject to 2 CFR Part 200, to the extent practicable. The core set of administrative requirements for participating Federal research agencies and other pertinent documents are posted on the National Science Foundation's web site. Recipients are encouraged to review the companion documents which include a Prior Approval Matrix, National Policy Requirement Matrix, Subaward Requirement Matrix, and Agency-Specific Requirements. NIH implementation of these Federalwide research terms and conditions is also known as the "NIH Standard Terms of Award".

See Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award for more details.

Guidelines and must establish a standing IBC. The IBC is required to review experiments involving recombinant or synthetic nucleic acid molecules to ensure that the procedures, project, personnel, and facilities are adequate and in compliance with NIH Guidelines. Section IV of NIH Guidelines specifies the composition of IBCs. A roster of the IBC members and biosketches for each member must be submitted to NIH. At a minimum, the roster should indicate the name of each IBC member, as well as which IBC members are serving as the chairperson, contact person, and, as applicable, experts in biosafety or plant, animal, or human experimentation. Biosketches should include a description of the occupation and professional qualifications of each member. Organizations can register their IBC with NIH on-line by utilizing the IBC Registration Management System (RMS).

4.1.26.3 Investigators and Institutional Staff

Section IV of *NIH Guidelines* also specifies the roles and responsibilities of PIs, biological safety officers (BSOs) and recipient institutions with respect to the safe conduct and oversight of recombinant or synthetic nucleic acid molecules. Investigators, laboratory staff, BSOs, and institutional officials should read and be aware of their duties and expected biosafety practices, as described by *NIH Guidelines*.

4.1.27 Research Misconduct

Title 42 CFR Part 93, PHS Policies on Research Misconduct (the "PHS regulation"), Subpart C, "Responsibilities of Institutions" specifies recipient responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity. Research misconduct is defined by Subpart A of 42 CFR Part 93 as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Subpart D, "Responsibilities of the U.S. Department of Health and Human Services," specifies that ORI has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities.

To be eligible for PHS funding, domestic and foreign institutions must have approved assurances and required renewals on file with ORI. The responsible institutional official must assure on behalf of the institution that the institution (1) has written policies and procedures in compliance with 42 CFR Part 93 for inquiring into and investigating allegations of research misconduct in PHS-supported research and (2) complies with its own policies and procedures and the requirements of 42 CFR Part 93. In addition, recipient institutions must foster a research environment that promotes the responsible conduct of research. Domestic and foreign subrecipient institutions must also maintain an assurance by submitting form PHS-6315 to ORI. An institution establishes an assurance when an official signs the face-page (SF 424 (R&R) or PHS 398) of the grant application form or when the institution files a separate assurance form. Once established, institutions maintain their assurance by filing the Annual Report on Possible Research Misconduct (between January 1 and April 30 each year), submitting their policy for responding to allegations of research misconduct for review when requested by ORI, revising their policy when requested by ORI to bring the policy into compliance with the PHS regulation, and complying with the PHS regulation.

As stated throughout the NIHGPS, the recipient has primary responsibility for ensuring that it is conducting its NIH-funded project in accordance with the approved application and budget and the terms and conditions of the award. The recipient must carry out its responsibilities with extra care where research misconduct has been found or where a research misconduct investigation has been initiated, as specified in 42 CFR Part 93, Subpart C. The recipient must report promptly to ORI any decision to initiate an investigation of research misconduct.

The regulations specify the timing of an institutional investigation, related reporting to ORI, notice to the respondent, custody of records, documentation, opportunity for respondent to comment on the report, and the components on a final institutional investigative report.

If a misconduct investigation is initiated, the recipient must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects and live vertebrate animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate. ORI staff members are available to provide technical assistance to any institution that is responding to an allegation of research misconduct involving PHS funds. NIH IC staff members are available to provide guidance and to work with recipient institutions to protect funded projects from the adverse effects of research misconduct.

The recipient institution's engagement with ORI as provided in 42 CFR Part 93 does not substitute for its engagement with NIH to ensure ongoing compliance with the terms and conditions of award. When the recipient institution finds, learns of, or suspects research misconduct that impacts or might impact the conduct or performance of an NIH-supported project(s), whether at the recipient organization or at a third-party subrecipient organization, the recipient must work with NIH to assess the effect on the ability to continue the project, as originally approved by NIH. If the recipient institution determines that a change of scope or a change of PD/PI or other senior/key personnel is required, the institution must promptly obtain approval from the NIH funding Institute or Center Grants Management Officer. When a recipient institution finds, learns, or suspects that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research, including but not limited to, applications for funding and progress reports, or published research or research products supported by NIH funds, NIH has a need to know this information, and the institution must immediately provide information on the affected research to the NIH Office of Extramural Research – Research Integrity (OER-RI), in a manner consistent with the ORI confidentiality provision at, 42 CFR Part 93.108. The final institutional investigation report must be submitted to ORI, as outlined in Subpart C of 42 CFR Part 93.

NIH retains the authority to provide oversight regarding the management of grants and cooperative agreements. Accordingly, NIH may take action(s) to protect the health and safety of the public, including research participants, to promote the integrity of the PHS supported research and research process, and to conserve public funds. When a recipient fails to comply with the terms and conditions of award, NIH may take one or more enforcement actions including disallowance of costs, withholding of further support, or suspension or termination of the grant. These actions are described in Administrative Requirements—Enforcement Actions.

Where research misconduct has affected data validity or reliability, ORI or NIH may request that the recipient and its employee/collaborator authors submit a correction or retraction of the data to a journal, publish the corrected data, or both. If the recipient does not comply, NIH may invoke its rights, under 2 CFR Part 200.315, to access the data (including copyrightable material developed under the award), and may then have the data reviewed, and notify the journal.

4.1.28 Seat Belt Use

Pursuant to EO 13043 (April 16, 1997), Increasing the Use of Seat Belts in the United States, NIH encourages recipients to adopt and enforce on-the-job seat belt policies and programs for their employees when operating vehicles, whether organizationally owned or rented or personally owned.

before taking action unless public health or welfare concerns require immediate action. However, even if a recipient is taking corrective action, NIH may take proactive actions to protect the Federal government's interests, including placing specific conditions on awards or precluding the recipient from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

8.5.1 Specific Award Conditions: Modification of the Terms of Award

During grant performance, the GMO may include specific award conditions in the grant award to require correction of identified financial or administrative deficiencies as a means of protecting NIH's interests and effecting positive change in a recipient's performance or compliance. When specific conditions are imposed, the GMO will notify the recipient in writing of the nature of the conditions, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the conditions. See 42 CFR Part 52.9 and 2 CFR Part 200.339.

The NIH awarding IC may withdraw approval of the PD/PI or other senior/key personnel specifically referenced in the NoA if there is a reasonable basis to conclude that the PD/PI and other such named senior/key personnel are no longer qualified or competent to perform the research objectives. In that case, the awarding IC may request that the recipient designate a new PD/PI or other named senior/key personnel.

Generally, the decision to modify the terms of an award (e.g., by imposing specific award conditions) is discretionary on the part of the NIH awarding IC and is not appealable.

8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

If a recipient has failed to comply with the terms and conditions of award, NIH may take one or more enforcement actions which include disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action. NIH may also terminate the grant in whole or in part as outlined in 2 CFR Part 200.340. The regulatory procedures that pertain to suspension and termination are specified in 2 CFR Parts 200.340 through 200.343.

a. NIH or the pass-through entity must provide the non-Federal entity a notice of termination
b. If the award is terminated for the non-Federal entity's material failure to comply with the Federal statutes, regulations, or terms and conditions of the Federal award, the notification must state that:
    1. The termination decision will be reported to the OMB-designated integrity and performance system accessible through SAM (currently FAPIIS);
    2. The information will be available in the OMB-designated integrity and performance system for a period of five years from the date of the termination, then archived;
    3. Awarding agencies that consider making a Federal award to the non-Federal entity during that five year period must consider that information in judging whether the non-Federal entity is qualified to receive the Federal award, when the Federal share of the Federal award is expected to exceed the simplified acquisition threshold over the period of performance;
    4. The non-Federal entity may comment on any information the OMB-designated integrity and performance system contains about the non-Federal entity for future consideration by HHS awarding agencies. The non-Federal entity may submit comments to the recipient integrity and performance portal accessible through CPARS.
    5. Federal awarding agencies will consider the non-Federal entity comments when determining whether the non-Federal entity is qualified for a future Federal award.
c. Upon termination of an award, NIH must provide the information required under FFATA to the Federal web site established to fulfill the requirements of FFATA and update or notify any other relevant government-wide systems or entities of any indications of poor performance as required by 41 U.S.C. 417b and 31 U.S.C. 3321. See also the requirements for Suspension and Debarment at 2 CFR Part 180.

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. However, NIH may decide to terminate the grant if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate a grant when necessary, such as to protect the public health and welfare from the effects of a serious deficiency. Termination may be appealed under NIH and HHS grant appeals procedures (see Administrative Requirements—Grant Appeals Procedures).

A grant also may be terminated, partially or totally, by the recipient or by NIH with the consent of the recipient. If the recipient decides to terminate a portion of a grant, NIH may determine that the remaining portion of the grant will not accomplish the purposes for which the grant was originally awarded. In any such case, NIH will advise the recipient of the possibility of termination of the entire grant and allow the recipient to withdraw its termination request. If the recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire grant.

See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost for the allowability of termination costs. Allowability of these costs does not vary whether a grant is terminated by NIH, terminated at the request of the recipient, or terminated by mutual agreement.

Withholding of support is a decision not to make a non-competing continuation award within the current competitive segment. Support may be withheld for one or more of the following reasons:

- Adequate Federal funds are not available to support the project.
- A recipient failed to show satisfactory progress in achieving the objectives of the project.
- A recipient failed to meet the terms and conditions of a previous award.

- For whatever reason, continued funding would not be in the best interests of the Federal government.

The recipient may appeal NIH's determination to deny (withhold) a non-competing continuation award because the recipient failed to comply with the terms and conditions of a previous award.

8.5.3 Other Enforcement Actions

Depending on the nature of the deficiency, NIH may use other means of promoting recipient compliance. Other options available to NIH include, but are not limited to conversion from an advance payment method to a reimbursement method or disallow (deny) all or part of the cost of the activity or action not in compliance. Other actions may include suspension or debarment of an organization or individual under Government-wide Debarment and Suspension rules provided at 45 CFR Part 76, and other available legal remedies, such as civil action. Suspension under 45 CFR Part 76, implementing E.O.s 12549 and 12689, "Debarment and Suspension," is a separate action from the "suspension" of an award as a post-award remedy, as described in Suspension, Termination, and Withholding of Support above. The subject of debarment and suspension as an eligibility criterion is addressed in Completing the Pre-Award Process—Determining Eligibility of Individuals and Public Policy Requirements and Objectives—Debarment and Suspension.

8.5.4 Recovery of Funds

NIH may identify and administratively recover funds paid to a recipient at any time during the life cycle of a grant. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost sharing, funds in the recipient's account that exceed the final amount determined to be allowable, or other circumstances. NIH guidance on the repayment of grant funds that are unrelated to audit findings can be found on the OER Web site.

8.5.5 Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L.104-134, 110 Stat. 1321, April 26, 1996); and, the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for HHS in 45 CFR 30. NIH is required to collect debts due to the Federal government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by recipients.

When NIH determines the existence of a debt under a grant, written debt notification will be provided to the recipient. Unless otherwise specified in law, regulation, or the terms and conditions of the award, debts are considered delinquent if they are not paid within 30 days from the date the debt notification is mailed to the recipient. Delinquent debts are subject to the assessment of interest, administrative cost charges, and penalties. The interest on delinquent debts accrues on the amount due beginning on the date the debt notification is mailed to the recipient.

If a recipient appeals an adverse monetary determination under 42 CFR Part 50, Subpart D, or 45 CFR Part 16, interest will accrue but assessment will be deferred pending a final decision on the appeal. If the appeal is not successful, interest will be charged beginning with the date the debt notification was mailed to the recipient, not the date of the appeal decision. Interest charges will be computed using the prevailing rate in effect on the date the debt notification is mailed, as specified by the Department of the Treasury and 45 CFR Part 30.13(a)(2).

A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment (PHS Form 2271). Individuals with a Conditional Permanent Resident status may be supported on Kirschstein-NRSA training grants; however, as with all types of Permanent Resident status it is the recipient's responsibility to assure the individual remains eligible for NRSA support for the period of time of any appointment. Individuals with Asylum/Refugee status do not automatically hold a form of permanent residency status; they have the opportunity to apply for permanent residency status once they have been in the U.S. for a period of time. Therefore, individuals with Asylum/Refugee status may not be appointed to a Kirschstein-NRSA training grant until they have also secured permanent residency status. Individuals on temporary or student visas are not eligible for Kirschstein-NRSA support.

11.3.3 Application Requirements and Due Dates

11.3.3.1 Application

All applications for Kirschstein-NRSA institutional research training grants are submitted electronically through Grants.gov and use an application package that combines form components from the SF424 (R&R) application along with the PHS398 components. Application forms and instructions are provided as part of each NOFO. Applicants should pay particular attention to the special instructions for institutional research training grants found in the SF424(R&R) Application Guide.

11.3.3.2 Due Dates

Several NIH ICs receive training grant applications three times each year; however, many ICs use only one or two receipt dates. Information on IC-specific receipt dates is available in the *NIH Guide for Grants and Contracts* in the NIH-wide T32 and T35 NOFOs and NOFOs issued by the individual NIH ICs or by contacting the appropriate NIH IC program official. For a list of the standard receipt dates and review cycle, see the NIH Standard Due Dates website. (Also see http://researchtraining.nih.gov.)

Applicants are encouraged to contact the appropriate NIH staff before preparing and submitting an application. Applications requesting funding of $500,000 or more in direct costs for any year must generally include a cover letter identifying the NIH staff member within the specific NIH IC who has agreed to accept assignment of the application. NIH ICs, however, may opt to forgo this requirement for certain types of grants, such as training grants; applicants should consult the Notice of Funding Opportunity for specific instruction and/or contact the NIH IC if there are questions about the applicability of this policy.

11.3.3.3 Special Program Considerations

The duration of training, the transition of trainees to individual support mechanisms, and their transition to the next career stage are important considerations in institutional training programs. Studies have shown that the length of the research training grant appointment of postdoctoral trainees with health-professional degrees strongly correlates to subsequent application for and success in receiving independent NIH research support. Therefore, Training PD/PIs should appoint only those individuals who are committed to a career in research and plan to remain on the training grant or in a non-Kirschstein-NRSA research experience for a minimum of 2 years in the aggregate. It also has been shown that transition to independent support is related to career success. Therefore, Training PD/PIs also should encourage and provide training in the skills necessary for postdoctoral trainees to apply for subsequent support through individual postdoctoral fellowships, mentored career development awards (K programs), or independent research project grants. When reviewing Kirschstein-NRSA institutional research training grant applications, peer reviewers will examine the training record to determine the average duration of training appointments for health-professional postdoctoral trainees and whether there is a history of transition to individual support mechanisms.

Programs located in clinical departments that focus on research training for individuals with the M.D. or other health-professional degrees should consider developing ties to basic science departments, or, if consistent with the goals of the program, modifying the program to include individuals with research doctorates. In these cases, applications should describe the basic science department's contribution to the research training experience and also indicate whether both health professional trainees and trainees with research doctorates will be included in the training program.

Training PD/PIs also must develop methods for ongoing evaluation of the quality and effectiveness of the training program. This should include plans to obtain feedback from current and former trainees to help identify weaknesses in the program and provide suggestions for program improvements as well as plans for assessing trainee's career development and progression, including publications, degree completion, and post-training positions. Evaluation results are to be included in competing continuation (renewal) applications and as part of the Final RPPR.

Within the framework of the program's longstanding commitment to excellence and projected need for investigators in particular areas of research, attention must be given to recruiting prospective trainees from diverse backgrounds, including racial or ethnic groups underrepresented in the biomedical, behavioral and clinical sciences, individuals with disabilities, and individuals from socially, culturally or economically disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research. Institutions are encouraged to identify candidates who will enhance diversity on a national or institutional basis. NIH's requirements for diversity recruitment and retention are described below.

11.3.3.4 Recruitment Plan to Enhance Diversity

Every facet of the United States scientific research enterprise—from basic laboratory research to clinical and translational research to policy formation–requires superior intellect, creativity and a wide range of skill sets and viewpoints. NIH's ability to help ensure that the nation remains a global leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will help to further NIH's mission.

Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust.

Underrepresented Populations in the U.S. Biomedical, Clinical, Behavioral and Social Sciences Research Enterprise

In spite of tremendous advancements in scientific research, information, educational and research opportunities are not equally available to all. NIH encourages institutions to diversify their student and faculty populations to enhance the participation of individuals from groups that are underrepresented in the biomedical, clinical, behavioral and social sciences, such as: