Summary of Significant Changes to the NIHGPS for April 2024 Version

The revised NIH Grants Policy Statement (NIHGPS, rev. April 2024) represents an update to the December 2022 version and is applicable to all NIH grants and cooperative agreements beginning on or after October 1, 2023. While the update does not introduce any new material for the first time, it incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the NIHGPS dated December 2022. The April 2024 revision supersedes, in its entirety, the NIH Grants Policy Statement (December 2022) as a standard term and condition of the award.

Notable Policy Changes: Implements new policies and provides clarification of existing policies that were previously announced in the NIH Guide for Grants and Contacts since December 2022 and listed at Notice of NIH Policy Changes.

| Section | Title | Comments |
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| All sections | GPS throughout | Replaced "prime recipient" with "pass-through recipient" for consistency with Uniform Guidance <u>2 CFR 200.332</u> . |
| All sections | GPS throughout | Replaced use of terminology from FOA (Funding Opportunity Announcement) to NOFO (Notice of Funding Opportunity) for consistency with Uniform Guidance <u>2 CFR 200.204</u> and <u>NOT-OD-23-109</u> (Updates to Funding Opportunity Terminology). |
| All sections | GPS throughout | Replaced use of term "commercial organization" with "for-profit" organization for consistency with Uniform Guidance terminology in <u>2 CFR Part 200</u> . |
| 1.2 | Glossary | Added entries for: Animal Welfare Assurance, For-profit Organization, Notice of Funding Opportunity. |
| 2.3.5.1 | Other Funding-Related Notices | Created a new section describing Notice of Intent to Publish (NOITP) and Request for Information (RFI). |
| 2.3.7.5 | New Investigators and Early Stage Investigators | Clarified the definition of Early Stage Investigator in line with NOT-OD-19-072 (Updates to NIH Policy on ESI Application Status). |
| 2.3.7.7 | Post-Submission Grant Application Materials | Added language to state that NIH will accept preliminary data as post-submission material under some circumstances in line with NOT-OD-23-106 (Revising the NIH/AHRQ/NIOSH Post-Submission Material Policy). |
| 2.3.7.10 | NIH Data Management and Sharing and Genomic Data Sharing | Revised heading from "NIH Genomic Data Sharing" to "NIH Data Management and Sharing and Genomic Data Sharing" and updated with high-level statement of DMS plan requirement for applications. |
| 2.3.9 | 2.3.9 Application Receipt Information and Deadlines | Added clarifying statement that electronic submission is generally required. |
| 2.3.9.1 | Electronic Submission Requirements | Revised heading from "Paper Applications" to "Electronic Submission Requirements" and stated requirements for required electronic submission of NIH applications. |

| 2.3.9.2 | On-time Application Submission | Revised heading from "Electronically Submitted Applications" to "On-time Application Submission" and stated requirements for on-time application submission. |
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| 2.3.9.2.1 | Late Applications | Added subsection heading "Late Applications" for clarity. |
| 2.3.9.3 | Continuous Submission for Appointed Members of NIH Federal Advisory Committees | Revised heading from "Modified Submission Policy for Appointed Members of NIH Review and Advisory Group and Reviewers with Recent Substantial Service" to "Continuous Submission for Appointed Members of NIH Federal Advisory Committees" and added language to clarify continuous submission requirements and criteria per updates provided in NOT-OD-20-060 (Update of NIH Continuous Submission Policy: Change in Submission Deadlines and End of Recent Substantial Service Option). |
| 2.3.9.6 | Natural Disasters and Other Emergencies | Added new section and content based on multiple reminder notices on NIH Extramural Response to Natural Disasters and Other Emergencies. |
| 2.5.1 | Just-in-Time Procedures | Added language from Other Support instructions that each PD/PI or other senior/key personnel must electronically sign their respective Other Support form prior to submission to certify that the statements are true, complete, and accurate. |
| 2.5.1 | Just-in-Time Procedures | Revised guidance, per NOT-OD-20-033 (NIH and AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for Research Training Grant, Fellowship, and Career Development Award Applications), to clarify the My Bibliography is collected via the Interim/Final Research Performance Progress Report. |
| 2.5.1 | Just-in-Time Procedures | Updated instructions for SBIR STTR Foreign Disclosure Form, per NOT-OD-23-139 (Implementation of the NIH SBIR and STTR Foreign Disclosure Pre-award and Post-Award Requirements). |
| 2.5.2 | 2.5.2 Submitting Revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement | Removed PDF file as an acceptable document format to send revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement. |
| 4.1.1 | Animal Welfare Requirements | Clarified foreign institution requirements under the Public Health Service Policy on Humane Care and Use of Laboratory Animals. |
| 4.1.1 | Animal Welfare Requirements | Clarified neither activities nor costs for activities for live vertebrate animals may be charged to NIH grants if there is not a valid Animal Welfare Assurance and IACUC approval of the activity. |
| 4.1.1.1 | Animal Welfare Assurance Requirements | Clarified neither activities nor costs for activities for live vertebrate animals may be charged to NIH grants without a valid Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW). |
| 4.1.1.2 | Verification of IACUC Approval | Clarified to require applicant verify there is congruence between the application and the Institutional Animal Care and Use Committee (IACUC)-approved protocol when it provides the IACUC approval date. |

| 4.1.1.4 | Foreign Recipients and Foreign Performance Sites | Clarified foreign recipients that will perform live, vertebrate animal activity onsite must provide OLAW with an Animal Welfare Assurance for Foreign Institutions. |
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| 4.1.1.4 | Foreign Recipients and Foreign Performance Sites | Clarified requirements and replaced "foreign organization's IACUC" with "foreign organization's animal welfare committee or oversight body". |
| 4.1.2 | Civil Rights Protections | Updated language to incorporate NOT-OD-23-047 (Updates to the Non-Discrimination Legal Requirements for NIH Recipients). |
| 4.1.3.3 | Good Cause Extension (GCE) Request Process | New section added based on NOT-OD-23-080 (Clinical Trials Results Information Submission: Good Cause Extension Request Process and Criteria Document Posted on ClinicalTrials.gov) and documents cited in that notice. |
| 4.1.10 | Financial Conflict of Interest | Edited to align with recent updates to Section 15.2 regarding the content of subrecipient agreements. |
| 4.1.15.2 | Certification of IRB Approval | Added language stating that NIH-funded sites in the United States cannot accept or rely on a non-US IRB and therefore, NIH will not accept an approval from a non-US IRB. |
| 4.1.15.10 | NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research | Added language clarifying that NIH expects sites located in the US to rely on a US Single Institutional Review Board for Multi-Site Research (sIRB). |
| 4.1.27 | Research Misconduct | Updated the end date for filing the Annual Report on Possible Research Misconduct from March 1 to April 30. |
| 8.1 | Changes in Project and Budget | Updated to state recipients are required to notify NIH of developments that have a significant impact on the award-supported activities as soon as they become known. |
| 8.2.3.1 | Policy for Data Management and Sharing (DMS Policy) | Revised section to incorporate current NIH DMS policy. |
| 8.2.3.1.1 | Genomic Data Sharing (GDS) Policy | Moved GDS to subsection of DMS (new section 8.2.3.1.1) from prior section (8.2.3.5). |
| 8.2.4 | Inventions and Patents | Revised government support clause to require grant number, including the two-letter institute code and six-digit serial number, and specify NIH as the Federal agency. |
| 8.4.1.5.2 | Financial Expenditure Reports | Updated section to replace OFM with the FFR Reconciliation and Financial Closeout Support Center (FFR-C) within OPERA as the entity which now receives and reviews expenditure data. |
| 8.4.1.5.3 | Revised Financial Reports and Expenditures | In line with NOT-OD-23-102 (Guidance for the Repayment of Grant Funds), added language clarifying that recipients must submit a revised FFR when a refund of \$20,000 or greater is due back to NIH, and that refunds under \$20,000 should be sent directly to PMS with instruction to post the funds to Miscellaneous Receipts. |

| 8.6.1 | Final Federal Financial | In line with NOT-OD-23-102 (Guidance for the Repayment of Grant Funds), added language clarifying that |
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| | Report | recipients must submit a revised FFR when a refund of \$20,000 or greater is due back to NIH, and that refunds |
| | | under \$20,000 should be sent directly to PMS with instruction to post the funds to Miscellaneous Receipts. |
| 11.2.2.3 | Degree Requirements | Revised predoctoral training to include basic biomedical or clinical sciences, in behavioral or social sciences, or in |
| | | health services research. |
| 11.2.9.2 | Stipends | Added statement to clarify that while stipends are not provided as a condition of employment, NIH policy is not |
| | | intended to discourage or otherwise prevent recipient institutions from hiring NRSA trainees and fellows as |
| | | employees or providing them with benefits consistent with what the institution provides others at similar career |
| | | stages per NOT-OD-23-111 (Reminder – NIH Policies for NRSA Stipends, Compensation and Other Income) |
| 11.2.12 | Changes in the Project | In line with NOT-OD-23-094 (NIH Redesign of the xTrain Module in eRA Commons), added language clarifying the |
| | | responsibilities of the two sponsoring organizations when a fellowship is transferred. |
| 11.3.2.5.1 | Predoctoral Training | Added language that defines dual degree program and clarifies eligibility for the predoctoral training program. |
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| 11.3.3.3 | Special Program Considerations | Removed "educationally" from "educationally disadvantaged backgrounds". |
| 11.3.3.3 | Special Program | Removed "retention" from NIH's requirements for diversity recruitment. |
| | Considerations | |
| 11.3.13.1 | Statement of Appointment | Per NOT-OD-23-094 (NIH Redesign of the xTrain Module in eRA Commons), added requirement that trainees sign |
| | (Form PHS 2271) | reappointments and amendments, just as they are required to sign the initial appointments. |
| 14.10.1 | Allowable Costs | Corrected language to state that when meals are justified by the applicant as an integral and necessary part of a |
| | | conference (i.e., a working meal where business is transacted), grant funds may be used for such meals, provided |
| | | that meal costs are not duplicated in participants' per diem or subsistence allowances. |
| 14.10.2 | Unallowable Costs | Removed meals as an unallowable cost. |
| 15.2 | Administrative and Other | Added language that NIH will not support any consortium agreement that does not meet minimum requirements |
| | Requirements | and NIH reserves the right to request copies of the written agreement as stated in NOT-OD-23-182 (NIH Final |
| | | Updated Policy Guidance for Subaward/Consortium Written Agreements). Added statement that NIH expects |
| | | recipients to ask potential subrecipients, at the application stage, to submit language in their letters of support |
| | | indicating their awareness of these requirements and the subrecipient's willingness to abide by all requirements |
| | | should an award be issued. |
| 15.2.1 | Written Agreement | As outlined in NOT-OD-23-182 (NIH Final Updated Policy Guidance for Subaward/Consortium Written |
| | | Agreements, added requirements that the formal written agreement between the recipient and each consortium |
| | | participant/subrecipient is signed and agreed to by both parties, a subaward cannot be issued if a subrecipient is |
| | | unwilling to sign the written agreement outlining the requirements in this section, and foreign subrecipients must |

| | provide the primary recipient access to copies of all lab notebooks, all data, and all documentation that supports |
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| | the research outcomes as described in the progress report no less than once per year, in alignment with the |
| | timing requirements for Research Performance Progress Report submission. |