E 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice to Announce NIH Updated Policy Guidance for Subaward/Consortium Written Agreements

AGENCY: National Institutes of Health, HHS.

ACTION: Request for comments.

SUMMARY: The National Institutes of Health (NIH) is seeking public comment on updates to the NIH Grants Policy Statement (GPS), Section 15.2, which outlines the requirements for consortium/subaward agreements on NIH-funded grants.

DATES: To ensure that your comments will be considered, please submit your response to this Request for Comments no later than [INSERT DATE 30 DAYS FOLLOWING DATE OF PUBLICATION IN THE FEDERAL REGISTER] to ensure consideration. The planned effective date of this guidance is October 1, 2023, and updated language will be incorporated into the GPS in the FY24 publication.

ADDRESSES: Comments may be submitted online at https://rfi.grants.nih.gov/?s=646e6654a8ba09024f09e852.

FOR FURTHER INFORMATION CONTACT: Xanthia James, Director, Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, Rockledge I, Suite 350, Bethesda, MD 20817. Email: Xanthia.James@nih.gov. Phone number (301) 435-0949.

SUPPLEMENTARY INFORMATION:

Request for Comments

NIH encourages the public to provide comments on any aspect of the updated guidance outlined below.

Submitting a Response

Comments should be submitted electronically to the following webpage https://rfi.grants.nih.gov/?s=646e6654a8ba09024f09e852 by the comment due date. Unedited comments will be compiled and may be posted, along with the submitter's name and affiliation, on the NIH Office of Extramural Research website after the public comment period closes. Submitted comments are considered public information. Please do not include any proprietary, classified, confidential, or sensitive information in your response.

Updated Guidance

2 CFR 200.332(a)(5) at https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR031321e29ac5bbd/section-200.332 states that subaward agreements must include, "a requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." In response to the Department of Health and Human Services (HHS), Office of Inspector General and Government Accountability Office audits, NIH has determined that to assure that this requirement is met, NIH finds it necessary to impose a requirement that foreign subrecipients turn over all records to the primary recipient at an agreed upon frequency (e.g., once a quarter, once a month). Therefore, section 15.2 is updated as follows (changes are **bold** and ***italicized***)

15.2 ADMINISTRATIVE AND OTHER REQUIREMENTS

The following highlights several areas within the consortium relationship that the recipient needs to address with consortium organizations receiving subawards under a grant to ensure compliance with NIH requirements. The requirement for a written agreement addressing these and other areas is specified in this section. ***NIH will not support any agreement that does not meet the minimum requirements outlined in the written agreement section below (15.2.1). NIH reserves the right to request copies of***

the written agreement and relevant supporting documentation as needed, as part of its oversight responsibilities. Failure to provide requested documentation may lead to remedies for noncompliance and potential enforcement actions (see 8.5, Specific award conditions and remedies for noncompliance).

NIH encourages 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.

Note that most of these requirements only apply to a recipient's consortium relationships with sub-recipients. When the relationship is with a vendor that is providing routine goods and services within normal business operations that are ancillary to the operation of the research program, the public policy requirements listed below do not apply. The vendor must also be providing similar goods and services to many different purchasers and provide them in a competitive environment.

15.2.1 Written Agreement

The recipient must enter into a formal written agreement***, signed, and agreed to by both parties,*** with each consortium participant***/subrecipient*** that addresses the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements of the grant, including those necessary to ensure compliance with all applicable Federal regulations and policies and facilitate an efficient collaborative venture. ***If a subrecipient is unwilling to accept the requirements outlined in this section, by signing a written agreement, then an agreement cannot be issued***. At a minimum, this agreement must include the following:

- Identification of the individual who will serve as the consortium lead investigator and other individuals responsible for the research activity at each consortium participant along with their roles and responsibilities.

- When multiple Program Directors/Principal Investigators (PDs/PIs) are involved at different organizations, only the Contact PD/PI is required to have the official relationship with the applicant organization. PDs/PIs in the leadership team at other organizations must have a documented relationship with a consortium organization but need not be employees. Any **consortium agreement** must address the unique aspects to these individuals holding the PD/PI role including the requirement for the prime institution to secure and retain all PD/PI signatures for all applications, progress reports, and post-award **prior approval** requests. Further, such signatures must be made available to NIH or other authorized HHS or Federal officials upon request. See Multiple Program Director/Principal Investigator Applications and Awards at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_9/9_multiple_program_director_principal_investigator_applications_and_awards.htm for additional information.
- Procedures for directing and monitoring the research effort.
- Procedures to be followed in reimbursing each consortium participant for its effort, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, procedures for review and approval of expenditures of grant funds at each organization and timing of applicable reporting requirements. This includes provisions on access to core facilities and resources and whether access will be provided as a fee-for-service.
- If different from those of the recipient, a determination of policies to be followed in such areas as travel reimbursement and salaries and fringe benefits (the policies of the consortium participant may be used as long as they meet NIH requirements).

- Terms that establish whether the Financial Conflict of Interest (FCOI) policy of the prime Institution or that of the subrecipient will apply to the subrecipient's Investigators.
- If the subrecipient's Investigators must comply with the prime Institution's FCOI policy, the subrecipient shall certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR Part 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the prime Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the prime Institution.
- If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the written agreement shall specify time period(s) for the subrecipient to report all identified FCOI to the prime Institution. Such time period(s) shall be sufficient to enable the prime Institution to provide timely FCOI reports, as necessary, to the Public Health Service (PHS) as required by the regulation.
- Alternatively, if the subrecipient's Investigators must comply with the prime Institution's FCOI policy, the written agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to the prime Institution. Such time period(s) shall be sufficient to enable the prime Institution to comply timely with its review, management, and reporting obligations under the 2011 revised FCOI regulation.
- A provision addressing ownership and disposition of data produced under the **consortium agreement**. This includes whether cell lines, samples or other resources will be freely available to other investigators in the scientific community or will be provided to particular investigators only.

- ***For foreign subrecipients, a provision requiring the foreign subrecipient to provide copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report. These supporting materials must be provided to prime recipient with each scientific update (no less than once every six months, or more frequently based on risks) in line with the timelines outlined in the agreement.***
- A provision making NIH data sharing and inventions and patent policy, including a requirement to report inventions to the recipient (see Administrative Requirements-Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm in IIA), applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the **consortium agreement** are protected and that the recipient can fulfill its responsibilities to NIH.
- Expectations for authorship and co-authorship on publications.
- Provisions regarding property (other than intellectual property), program income, publications, reporting, and audit necessary for the recipient to fulfill its obligations to NIH.
- Provisions regarding compliance with requirements for a Unique Entity Identifier (UEI) and subrecipient reporting under the Federal Funding Accountability and Transparency Act (FFATA) (see Recipient Reporting of Subrecipient Data and Executive Compensation Information for FFATA at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm#Recipient). Note, the recipient must provide the Federal Award Identification Number (FAIN)

at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.1_abbreviations.htm#FAIN to all subrecipients to aid in this requirement.

- Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm in IIA).

See NIH Guide Notice NOT-OD-23-133 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-133.html.

Dated: May 30, 2023.

Tara A. Schwetz,

Acting Principal Deputy Director,

National Institutes of Health.

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