NIH Foreign Subaward Requirements Guidance for Administrators and Principal Investigators

December 2023

Overview

The Harvard University foreign subrecipient data access policy (Data Access Policy), effective January 1, 2024, was established to meet the National Institutes of Health (NIH) requirements regarding subawards and to implement enhanced monitoring, documentation, and reporting requirements for recipients with a foreign subrecipient. See "Final Updated Policy Guidance for Subaward/Consortium Written Agreements" (NOT-OD-23-182. September 15, 2023). The policy only applies to grants/cooperative agreements funded by the NIH.

The Data Access Policy states that when issuing subawards under a NIH grant or cooperative agreement, Harvard University requires that Principal Investigators have access to the subrecipients' records supporting the research outcomes. To implement this requirement in all active and new NIH grants, all foreign subrecipients must provide access to copies of all records that support the research outcomes as described in the Research Performance Progress Report (RPPR).

It is important to emphasize that this access is only to lab notebooks, data, and documentation that support the research outcomes as described in the progress reports.

To implement the Data Access Policy, the foreign subrecipient must agree to abide by the NIH requirements in writing in Statement of Intent forms and in all active and new NIH subaward/consortium agreements with foreign subrecipients.

Guidance

All Principal Investigators (PIs) and administrators at Harvard University within all schools, units, divisions, University-wide initiatives, and centers who are involved with the negotiation and administration of NIH-funded subawards to a foreign subrecipient must comply with the University's Foreign Subrecipient Data Access Policy.

All PIs and research administrators associated with NIH-funded foreign subawards should be made aware of the NIH foreign subaward requirements along with the NIH guidance, which notes:

> ***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).***
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> ***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.***
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> ***15.2.1 Written Agreement***
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> ***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:

Note: All current requirements remain in place, with the addition of:

For foreign subrecipients, a provision requiring the foreign subrecipient to provide access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report, to the primary recipient with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission. Such access may be entirely electronic.

Implementation

Proposal Stage:

The following provision is required by Harvard University in all new NIH subaward/consortium Statement of Intent (SOI) forms from foreign subrecipients in response to NIH's policy expectations:

The subrecipient organization agrees to abide by the requirements of the NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreement (NOT-OD-23-182), and will provide access to copies of all lab notebooks, all data, and all documentation that support the research outcomes as described in the progress report, to the primary recipient with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission. Such access may be entirely electronic.

The following provision is expected per NIH policy in all new subaward/consortium Letters of Support (LOS) from foreign subrecipients' Principal Investigators (PIs):

I agree to provide you with access to copies of all lab notebooks, all data, and all documentation that support the research outcomes as described in the progress report, with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission. Such access may be entirely electronic.

Award and Subcontract Stage:

A new provision must be added per NIH policy in all active and new NIH subaward/consortium agreements with foreign subrecipients that addresses data access. Harvard advises the use of the following language:

[Subrecipient name] agrees to provide access to copies of all lab notebooks, all data, and all documentation that support the research outcomes as described in the progress report, to [primary recipient] with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission, per the attached implementation Plan. Such access may be entirely electronic

Roles and Responsibilities

Roles and Responsibilities for PIs, Grant Managers, and Central Research Administration Offices are provided in the Foreign Subrecipient Data Access Policy.

Guidance for Principal Investigators

- Consider the following information needed from subrecipient to prepare Implementation Plan:
    - Coordinate with research administration of obtaining details of the research data files and timing to access/review (see Checklist for suggested questions).
    - Review preferred method of direct access to their record site, electronic logbooks, etc.
    - Determine a common data repository for data and share site (e.g., SharePoint, Dropbox, Box, Google Drive, etc.).
- Manage the development of an Implementation Plan (addendum to the Data Management Plan) with the subrecipient on means of access, such as:
    - Method of direct access to their records site, electronic logbooks, etc.
    - Confirm the data repository for data and share site (e.g., SharePoint, Dropbox, Box, Google Drive, etc.).
    - Include a provision detailing the timing of accessing copies of the foreign subrecipient's records supporting the research outcomes.
    - If the subrecipient's records include personally identifiable information and/or information in a foreign language, the implementation plan must also include a provision requiring the foreign subrecipient to de-identify information and/or translate the information into English, if requested by the University to meet regulatory requirements.
- Submit and Review the implementation plan with the responsible Data Security Officer to ensure that it meets all applicable data security, privacy, and IRB requirements for all subrecipient awards.
    - Data Management Plans may be submitted via the Data Safety Portal (use the Safety Tab in Data Safety System for Safety Submission)
- Review the relevant records at least annually to confirm that the performance outcomes that are reported in the RPPR are accurate, complete, and properly reflect programmatic goals.
- Attest in the RPPR confirming the subrecipient records have been reviewed at least annually by including the following statement in the Accomplishments Section of RPPR:
    - *I confirm that I have reviewed the relevant foreign subrecipient documents that support the research outcomes as described in the progress report, with a frequency of no less than once per year, in accordance with the NIH policy regarding subawards with foreign entities (NOT-OD-23-182).*

Guidance for Administrators

- Ensure the Subaward/Consortium Statement of Intent includes the relevant language.
- Obtain details on the research data and documentation (see Checklist for questions to ask the subrecipient regarding the data to be accessed)
- Ensure final sub-agreement is signed and includes:
    - The NIH foreign subrecipient data access provision
    - The subaward agreement must include a provision detailing the method for and timing of accessing copies of the foreign subrecipient's records supporting the research outcomes.
    - If the subrecipient's records include personally identifiable information and/or information in a foreign language, the subaward agreement must also include a provision requiring the foreign subrecipient to de-identify information and/or translate the information into English, if requested by the University to meet regulatory requirements.
- Monitor compliance with the RPPR due date/notice and confirm that the RPPR includes the PI attestation referenced above in the Accomplishments Section.

Related Policies and Guidance

- Negotiating and Signing Authority for Agreements Related to Research
- Subrecipient Monitoring Policy
- Subrecipient Monitoring Toolkit
- Frequently Asked Questions