HARVARD
UNIVERSITY

Policy on Access to Foreign Subrecipient Records Funded by NIH Grants/Cooperative Agreements

Effective Date: January 1, 2024

Policy Date: December 15, 2023

Responsible Office: Office of Sponsored Programs, Harvard Medical School Office for Research Administration, and Harvard School of Public Health Sponsored Programs Administration

Policy Statement

When issuing subawards under a National Institutes of Health (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).

Reason for Policy

The policy is established to meet the 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).

Who Must Comply

All Principal Investigators 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 this Policy.

Implementation of Policy

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.

If a subrecipient is unwilling to accept the NIH requirements for subrecipient agreements outlined above, by signing a written agreement, then an existing subaward shall be terminated, and appropriate termination notices shall be provided before the compliance date set by NIH.[1]

Roles and Responsibilities

Principal Investigators take primary responsibility for ensuring compliance with Federal regulations as well as the monitoring of subrecipient progress, expenditures, timely correction of errors, and proper allocation of expenses. Within the context of this Policy, the PIs' responsibilities include:

- Informing the PI of the foreign subrecipient of the Policy requirements.
- Developing an implementation plan with the PI of the foreign subrecipient that includes:
    - Means of access to the records (all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report)
    - 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 the implementation plan in the Harvard Data Safety Portal for review by the responsible Data Security Officer to ensure that it meets all applicable data security, privacy, and IRB requirements.
- Reviewing 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 that the subrecipient records have been accessed and reviewed. The attestation requirement will be met by including the following statement in the Accomplishments Section of the 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).*

[1] Active subrecipient written agreements need to be in compliance with the NIH data access provision by June 30, 2024.

Grant Managers are responsible for facilitating and directly assisting the PI with the administrative elements of the research life-cycle. Within the context of this Policy, the Grant Managers' responsibilities include:

- Proposal Stage: Coordinating with subrecipient grant administration staff to ensure that the subrecipient Statement of Intent (SOI) includes the required language indicating the foreign subrecipient is aware of the data access requirements and is willing to abide by all requirements should an award be issued. (*Note: if the subrecipient SOI does not include this language, Harvard's SOI should be used*. *See SOI templates below.)*
- Proposal Stage: Coordinating with subrecipient grant administration staff to ensure that the subrecipient PI LOS includes the expected language indicating the PI of the foreign subrecipient is aware of the data access requirements and is willing to abide by all requirements should an award be issued. This language should be included in the LOS, unless including the provision would cause undue burden or delay.
- Award Stage: Informing the PI of the requirement to develop an implementation plan with the foreign subrecipient. Providing the documents required for an outgoing subaward or subamendment – updated scope of work, updated budget, and implementation plan. Ensuring the written agreement with the subrecipient includes the required language indicating the subrecipient's awareness of the data access requirements and its willingness to abide by all requirements.
- RPPR Stage: Facilitating the completion and submission of the RPPR before the deadlines and confirming the PI has attested to the access and review of the subrecipient data and documentation that supports the research outcomes reported in the progress report.

Central Research Administration Offices (HMS ORA, HSPH SPA, and OSP) are responsible for:

- Proposal Stage: Ensure that the subrecipient Statement of Intent (SOI) includes the required language indicating the foreign subrecipient is aware of the data access requirements and is willing to abide by all requirements should an award be issued.
- Award Stage: Entering into a formal written agreement, signed, and agreed to by both parties, with each 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.
    - The formal written agreement must contain the provision noted above indicating the subrecipient's awareness of the data access requirements and its willingness to abide by the requirements.
    - The formal written 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.
  - If a subrecipient is unwilling to accept the requirements outlined above, by signing a written agreement, then an agreement cannot be issued, and appropriate termination notices shall be provided.

- RPPR Stage: Completing review and submission of the RPPR before the deadlines and confirming the PI has attested to the access and review of the subrecipient data and documentation that supports the research outcomes reported in the progress report.

Policy Exceptions

There are no exceptions to the NIH requirement to add the data access provision to all foreign subaward agreements.

Definitions

Foreign Subrecipient – A subrecipient located in a country other than the United States and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance.

Subaward - An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements.

Subrecipient - A non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency. The term includes consortium participants.

Related Policies and Guidance

- Negotiating and Signing Authority for Agreements Related to Research
- Subrecipient Monitoring Policy
- Subrecipient Monitoring Toolkit
- PDF of NIH Foreign Subaward Requirements Guidance
- NIH Foreign Subaward Checklist Excel Spreadsheet
- Frequently Asked Questions

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Other Schools	Contact your OSP Rep with Questions

Contact the appropriate Central Research Administration Offices (HMS ORA, HSPH SPA, or OSP) for access to foreign subrecipient records written agreement information.