Foreign Subrecipients on NIH Projects: Data Access Roles and Responsibilities

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In response to Notice NOT-OD-23-182, UNC Chapel Hill's Office of the Vice Chancellor for Research (OVCR) provides the following written guidance and resources to assist the research community in complying with these requirements.

Summary of Requirements:

Effective January 1, 2024, NIH is requiring recipients to include a term in their subaward agreements that explicitly requires foreign subrecipients to provide access to all records related to the NIH funded research described in progress reports. The access should include copies of all lab notebooks, all data, and all documentation that supports the research outcomes and must be available at least once per year. Such access can be entirely electronic.

For more detailed information on requirements consult the FAQ's section of this document.

OVCR Responsibilities and Resources:

The Office of Sponsored Programs (OSP) will ensure that the appropriate contract language is incorporated into all subawards per NIH's requirements. The new language will include a standard clause requiring the foreign sub-recipients to provide **access to all relevant data for UNC's Lead Principal Investigator** (Lead PI). Modifications to existing foreign subawards will be issued soon. OSP is also planning to share a brief explanation of the new requirement with all foreign subrecipients. If you receive questions from NIH or the foreign subrecipients related to the agreements, feel free to direct them to OSP.

What is Lab Archives:

Electronic research notebooks (ERNs) help researchers manage results of research efforts, record and document research processes and procedures, and manage research data in ways that increase reproducibility, efficiency, collaboration, searchability, and security.

To use Lab Archives:

1. Register for a LabArchives account using your institutional email address.
2. Create a notebook for your research project and invite your collaborators to join.
3. Upload your existing lab notebooks, data, and documentation to your notebook or create new entries using the web interface or the mobile app.
4. Organize your notebook using folders, tags, comments, and links.
5. Use the tools and integrations available in LabArchives to enhance your research workflow, such as data analysis, citation management, and file sharing.
6. Export or archive your notebook when your project is completed or when required by the regulatory authority.

For more information and guidance on how to use LabArchives, please refer to the UNC's LabArchives website https://research.unc.edu/systems/labarchives/

Note: **LabArchives is not cleared to handle or store HIPAA, PHI, FERPA, CUI or other regulated data; however this information may be redacted in LabArchives.**

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Lead PI and Research Team Responsibilities:

Ensure progress reports and all other required lab notebooks and data are accessible and support the research outcomes at least once per year in alignment with RPPR submissions.

Foreign subrecipients should include the following language in their letters of support. The Lead PI and research team should share this language with all foreign subrecipients included in the proposal.

> We, the subrecipient organization, will provide periodic progress reports to UNC Chapel Hill that includesaccess to all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report. We also agree to abide by all requirements of NIH Updated Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-133), including the budget, scope of work, performance period, reporting obligations, and other terms and conditions. We certify that we have the necessary resources, expertise, and facilities to carry out the proposed research activities and to comply with the applicable policies and regulations."

Work collaboratively with OSP and UNC's Research Science and Security (RSS) to maintain subrecipient relationships including help in explaining the purpose and source of these new requirements.

Note: There is not a required, specified method of compliance. The primary requirement is that the **Lead Principal Investigator have "access"** (even if entirely electronic) to **all NIH foreign subrecipient data that supports the yearly RPPR**.

FAQs:

Note: These FAQs are taken directly from NIH's webpage.

1. How did we get here?

NIH is implementing this new policy in response to an unfavorable audit finding by the Office of the Inspector General (OIG). This language is from the policy update; "2 CFR 200.332(a)(5) 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.'"

2. What does NIHs Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-182) mean for foreign subawards established before the January 1, 2024 implementation date?

NIH expects recipients to update existing foreign subaward agreements within 60 days of the effective date to address the requirements outlined in NOT-OD-23-182

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3. **If a recipient organization has a large number of foreign subaward agreements to update to comply with NIHs Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-182) can they request an extension?**

Yes.

NIH recognizes that recipients may need additional time depending on the number of agreements an institution has in place for each project. Therefore, extensions may be requested, if needed, by contacting the Office of Policy for Extramural Research Administration at grantspolicy@nih.gov.

4. **What is the prime recipient responsible for once they receive documentation supporting research outcomes from the foreign subrecipient?**

Prime recipients should continue to review all subaward documentation to confirm that the performance outcomes that are reported in the Research Performance Progress Report (RPPR) are accurate, complete, and properly reflect programmatic goals, as stated in the RPPR.

5. **What is the expectation for retention of supporting documentation provided by foreign subrecipients to the prime? Would this information ever need to be provided to NIH?**

NIH expects all institutions to apply the current record retention policies as outlined in the NIHGPS 8.4.2 Record Retention and Access, which implements 2 CFR Part 200.334. In other words, recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the final FFR is submitted to NIH. As outlined in the GPS 8.4.2, which implements 2 CFR Part 200.337, recipients must provide access to NIH upon request.

6. **How does the NIHs Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-182) affect NIH's foreign prime recipients?**

This policy requirement applies to all subaward arrangements. NIHs Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-182) specifically calls out domestic prime recipients who are responsible for overseeing foreign subrecipients as that was a focus of an Office of Inspector General's audit findings.

7. **There have been concerns expressed that NIHs Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-133) unfairly singles out foreign subawardees and potentially undermines NIHs efforts towards diversity, equity, and inclusion and reaching underserved communities.**

Both the Office of Inspector General (OIG) and the General Accounting Office (GAO) audits of NIH explicitly called out foreign subrecipients and one called out specifically the unique challenges that domestic prime recipients face when dealing with foreign subrecipients.

We understand that foreign subrecipients are diverse, and that a number of them may have less resources than others. We're hoping that by making it clear that using commonly used digital platforms will help to enable everybody to be compliant with this long-standing regulatory requirement. The general principle of compliance with terms and conditions of award, and with access to materials that support a progress report, apply to all.

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8. **What happens if a foreign organization is subject to local laws or policies which conflict with NIH requirements for making copies of documentation that supports research outcomes available to the domestic prime institution?**

There are three points to keep in mind. (1) Recipients, prime recipients as well as subrecipients, have to be compliant with terms and conditions of award. The prime recipients are responsible to the NIH, and then those terms and conditions flow down to the subrecipient. . (2) NIH expects that all recipients, as well as subrecipients, will follow all applicable state and local laws. (3) If there is a concern about whether or not local laws or rules or regulations may affect ability to be compliant with terms and conditions of award, the recipient and/or subrecipient should consult with their general counsel on the facts of the specific situation.

9. **NIH's data sharing policy explicitly does not require the sharing of lab notebooks. Can you discuss the difference between the policies on oversight of foreign subawards and data sharing?**

The two policies are distinct. Data sharing is about what we expect grant recipients to share with the public. The NIH requirement for foreign subawardees to provide the prime awardee with access to notebooks and other documentation that support research outcomes reported in the RPPR has to do with what information collaborators must share with each other to support award oversight and compliance.

10. **When providing access to subrecipients' copies of lab notebooks, data, and documentation to support the research outcomes as described in the progress report, as required by NIHs Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-182), how shall prime recipients balance these access requirements with limitations set by a Research Ethics Board and/or Institutional Review Board (e.g., participant privacy requirements)?**

Limitations on data access, for protection of personally identifiable information applies to the updated foreign subrecipient/consortium written agreement requirements that require foreign subrecipients to provide the prime recipient with access to notebooks and other documentation that support research outcomes reported in the research performance progress report (RPPR). Therefore, personally identifiable information can be redacted to protect participant privacy. See NIH Grants Policy Statement (GPS) Section 4.1.4 and Section 15.2.1 for more information regarding requirements for protection of identifiable, sensitive information collected by the prime recipient or subrecipients.

If you have any questions or concerns, please reach out to Quinton Johnson at quinton@unc.edu who will direct you to the appropriate subject matter expert.

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