

Foreign Subrecipients on NIH Projects: Data Access Requirements



Summary of Requirements:

Effective January 1, 2024, NIH issued NOT-OD-23-182, which clarifies **prime recipients' responsibilities** related to **subrecipients** at the application stage and after award.

Data Access Requirements:

UNC and Lead Principal Investigators must:

- Verify that foreign subrecipients provide access to all lab notebooks, all data, and all documentation that supports the research outcomes as described in the yearly progress report.
- Retain access to records pertinent to the entire competitive segment for 3 years from the date the Final Financial Report (FFR) is submitted to NIH.

Proposal Language Requirements:

For new NIH proposals, foreign subrecipient sites must include the following language in their letter of support:

We, the subrecipient organization, will provide periodic progress reports to UNC Chapel Hill that includes access 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."

The Office of Sponsored Programs (OSP) will ensure any NIH required contractual terms are included in all new and existing foreign subawards.

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

OVCR-Provided Compliance Tools:

Use of LabArchives is an optional solution provided by UNC's OVCR, alternative means are acceptable provided they comply with the NIH requirement.

Lab Archives:

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.

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.

For more information and guidance on how to use LabArchives, please refer to the UNC's LabArchives website.