Complying with NIH's Data Access Requirement for Foreign Subrecipients

The purpose of this memo is to provide guidance to the research community on NIH's data access requirement for foreign subrecipients. It is organized in the following sections:

Please contact the GCO with any questions you may have.

I.   NIH Policy

NIH issued a notice, NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-182), effective January 1, 2024 requiring that agreements with foreign subrecipients on grants and cooperative agreements include a clause that gives the prime institution access to copies of all lab notebooks, data and documentation that support the research outcomes reported in the Research Performance Progress Report. See the notice text below.

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.*

If a subrecipient is unwilling to accept the requirements outlined in this section, by signing a written agreement, then an agreement cannot be issued.

II.   Data Sharing Repository

Mount Sinai is using LabArchives as an electronic solution to comply with the NIH data access requirement. LabArchives is a web-based application designed for scientists to organize and share data with colleagues around the world.

Features

- Mount Sinai PI can create notebook(s) for subrecipients and their team members for ongoing use.
- Subrecipients can scan existing notebooks (if paper) and upload to Electronic Lab Notebook (ELN).

- Provide read-only access to templates/custom resources to be used across the project via a separate resource notebook.

If you wish to propose another data sharing repository platform in lieu of LabArchives because your grant has atypical features, please contact your designated AOR who will review these requests on a case by case basis. Please note that exceptions will only be made when there is a true unlike circumstance.

IMPORTANT: Foreign subrecipients must not upload or otherwise disclose to LabArchives any personally identifiable information (PII), protected health information (PHI), "personal data" as defined by and subject to the General Data Protection Regulation (GDPR), or any other data relating to an identified or identifiable natural person that is subject to any other applicable data protection laws, rules, regulations, or legal requirements (collectively, "Personal Data") Prior to uploading or otherwise disclosing to the LabArchives any data, documents, or other materials to comply with the NIH access guidance, subrecipients must completely redact or otherwise anonymize such materials so that they contain no Personal Data.

As the Mount Sinai PI, you and your team must not use LabArchives to combine Mount Sinai data with foreign subrecipient data. The subrecipient data must be stored and maintained in a separate notebook. The creation of LabArchives notebooks for foreign subrecipients is done solely for the purpose of facilitating subrecipients' compliance with the NIH access guidance. Once the foreign subrecipient uploads the lab notebook(s), data, or documentation to LabArchives, Mount Sinai personnel must not download, transfer, or otherwise use uploaded materials except in connection with complying with NIH access requests in coordination with the GCO.

III.   Proposal Submission Process

GCO has updated the Subaward Statement of Intent (SOI) and requires that foreign subrecipients either use this form or equivalent language. When a user selects "Yes" to the NIH Foreign (Non U.S.) Subaward question on the GCO SOI form, the necessary language appears as follows:

> **Foreign (Non U.S.) Subaward on NIH Grants**
> I confirm as the Signing Official for a foreign subaward on an NIH grant, my Institution will 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 the Research Performance Progress Report submission. Such access may be entirely electronic, but will be via a method determined by the Prime Institution.
> Personal data may be redacted by foreign subrecipient to comply with regulations set forth by the subrecipient's local data laws.

Submit the SOI to GCO as part of submission process through InfoEd. More information about the process can be found in GCO's Documentation and Guidance for Subawards when Mount Sinai is the Prime Institution.

A foreign subrecipient that does not provide the required data access language will be removed from the project.

IV. Existing and Future Subaward Agreements

GCO has contacted the PIs of already existing grants/cooperative agreements with foreign subrecipients and informed the PI of the NIH policy, the use of LabArchives and instructions on creating a notebook and adding the foreign subaward recipient PI. Sponsored Project Finance (SPF) will continue to perform this task on new agreements.

Sponsored Project Finance (SPF) has begun working on issuing subaward amendments to existing projects and will issue new subaward agreements with the relevant data access language. When issuing the amendment or agreement, SPF also provides LabArchives instructions to the foreign subaward recipient for uploading data and notebooks, and documentation.

V. PI Responsibilities

The PI's responsibilities are as follows:

- Create an ELN account if you do not already have one
- Create a lab notebook for the foreign recipient, and invite the foreign subrecipient PI.   Please click here for LabArchives instructions. Please note this notebook should not be a notebook you are also using to upload data and if you have more than one foreign recipient, they should each have their own.
- Ensure that the required study information is uploaded as part of RPPR preparation.
- While the subaward agreement terms require the subrecipient to redact PII, PHI, and other personal data regulated by data protection laws and regulations (including EU data subject to the GDPR), if you become aware that any such personal data has been uploaded to LabArchives, you should promptly request that the subrecipient delete any such data. If you have any questions about the use of data on LabArchives, please contact the GCO.
- Ensure that if the data and/or documents is in a foreign language, that a translation is provided. Please refer to this NIH FAQ.
- Retain project records as required by ISMMS data retention policy and the NIH data retention policy.
- Beginning July 1, 2024, add this attestation to the Accomplishments Section of the RPPR: "As the PI and/or Contact MPI, 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)."

VI. Links and Resources

This section includes links and other resources to comply with the NIH data access requirement.

NIH
- NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements (NOT-OD-23-182
- NIH FAQs on Data Access for Foreign Subrecipients
- NIH Data Retention Policy

GCO

- [Documentation and Guidance for Subawards when Mount Sinai is the Prime Institution](#)
- [Subaward/Consortium Statement of Intent Template: ISMMS as the Prime Institution](#)
- [LabArchives Instructions for Mount Sinai PI](#)
- [LabArchives Instructions for Foreign Subrecipient PI](#)

Other ISMMS Resources

- [ISMMS Data Retention Policy](#)