

UCLA Office of Contract and Grant Administration
NIH Foreign Subaward Guidance

Overview

On January 1, 2024, a National Institutes of Health (NIH) policy went into effect requiring enhanced monitoring, documentation and reporting requirements for subawards to international entities under NIH funded grants and cooperative agreements. See “Final Updated Policy Guidance for Subaward/Consortium Written Agreements” ([NOT-OD-23-182. September 15, 2023](#)).

Under this new policy, UCLA Principal Investigators need to ensure they have access to their international subrecipients’ lab notebooks, data, and documentation supporting the research outcomes as described in the Research Performance Progress Report (RPPR). This access may be electronic. At proposal stage, NIH expects UCLA to include Letters of Support from proposed international subrecipients confirming their awareness of this requirement. At award stage, UCLA must include a term in its written subaward agreements to international subrecipients requiring this provision of access to lab notebooks, data, and documentation supporting the research outcomes as described in the Research Performance Progress Report (RPPR).

Guidance

Proposal Stage - Department:

UCLA’s Subrecipient Letter of Intent (LOI) has been updated to include a section for the subrecipient institution’s confirmation of NIH’s new policy. Please make sure that any international subrecipients under proposed NIH grants and cooperative agreements are completing this section of the LOI:

NIH International Subrecipient Reporting Requirements <i>(For non-U.S. Subrecipients only.)</i>	
<input type="checkbox"/>	If the prime sponsor is the U.S. National Institutes of Health (NIH), Subrecipient is aware of the provisions of NIH GPS 15.2.1 requiring that international subrecipients provide access to copies of all lab notebooks, data, and documentation that support any resulting research outcomes, and Subrecipient confirms that it is able to comply and provide UCLA with regular access to these materials (i.e. annually) for the life of the subaward.

NIH expects language reflecting the new policy to be included in proposal Letters of Support from international subrecipients’ Principal Investigators (PIs). The following language is recommended for inclusion:

I agree to provide UCLA access to copies of all lab notebooks, all data, and all documentation that supports 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. I will work with the UCLA PI before commencing work on the project, to agree to details of how information will be shared, including format, access and frequency.

Award and Subaward Stage - Department:

As soon as a grant/cooperative agreement is received from NIH and setup at UCLA, and when the department is ready to proceed with its subaward to an international subrecipient, the department will need to submit a subaward request package to OCGA’s Outgoing Subawards Team (see <https://ocga.research.ucla.edu/award-stage-procedures/> for reference). This request package will include the [OCGA Subaward Checklist](#). On page 2 of the [OCGA Subaward Checklist](#), be sure to complete the section titled ‘NIH International Subrecipient Data Collection Requirement.’

Award and Subaward Stage - OCGA:

The UCLA Office of Contract and Grant Administration (OCGA) will add terms outlining this data access requirement to all active and new NIH subaward agreements with international subrecipients.

Amendments to active NIH subaward agreements with international subrecipients will include the following language:

Per NIH NOT-OD-23-182, as of January 1, 2024, Subrecipient must provide PTE with access (which may be electronic) to copies of all lab notebooks, all data, and all documentation associated with the research outcomes as described in Subrecipient's progress report(s), including final progress report and case reports. This access must be provided with a frequency of no less than once per year, in alignment with the timing of Subrecipient's progress report submission(s), and at PTE's request. By signing this agreement amendment, Subrecipient certifies that it will comply with this requirement.

New NIH subaward agreements to international subrecipients will include the following language:

[Attachment 1:] Per NIH NOT-OD-23-182, Subrecipient must provide PTE with access (which may be electronic) to copies of all lab notebooks, all data, and all documentation associated with the research outcomes as described in Subrecipient's progress reports, which includes case reports, to PTE. This access must be provided at least once a year and at PTE's request. By signing this agreement, your organization certifies that it will comply with this requirement.

[Attachment 4:] Access to copies of all lab notebooks, all data, and all documentation associated with the research outcomes shall be provided annually, in alignment with the timing of the progress report(s) submission(s) listed above, and at PTE's request. Subrecipient must submit securely to the PTE Principal Investigator with copy to the PTE Financial Contact listed in Attachment 3.

Guidance for Principal Investigators

- Consider the following questions when discussing data access with your subrecipient:
 - What types of files does your subrecipient expect to be providing?
 - Hardcopies?
 - How will hardcopies be digitized?
 - Electronic?
 - What type of electronic file?
 - What software is used to create the records?
 - Will software be needed to read the records?
 - What are the expected sizes of files?
 - What is the preferred method of access?
 - Will files include personally identifiable information (PII)?
 - PII may need to be removed and information de-identified prior to sharing
 - Are there any third-party data licensing requirements?
 - Should a data repository be setup?
 - Ex. SharePoint, Dropbox, Box, Google Drive, etc.
 - When will access be needed?
 - How far in advance of the RPPR?
 - How often will access be needed?

- Steps you will want to take once your subaward is setup:
 - Confirm setup of the data repository
 - Confirm access to data
 - Review data at least once annually to confirm that it is properly reflected in the RPPR
- NIH will also require the completion of an attestation in the RPPR, confirming the subrecipient records have been received and reviewed
- Monitor compliance with the RPPR due date/notice.
- Ensure that data and documents collected from the subrecipient are retained by UCLA (i.e. on UCLA servers) for at least 3 years following submission of the project's final financial report to NIH.

Related NIH Guidance

Policy FAQs: <https://grants.nih.gov/faqs#/subawards.htm?anchor=4304>

NIH Subawards Page: <https://grants.nih.gov/policy/subawards>

Open Mike blog post: <https://nexus.od.nih.gov/all/2023/09/15/further-clarifying-nih-foreign-subaward-agreement-policy-addressing-community-feedback/>