



Office of Contract & Grant Administration Updates

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Research Administration Forum

Tracey Fraser, Sr. Director OCGA

Topics

NIH Foreign Component And Other Disclosure Requirements

NIH International Subawards

Other Updates



NIH Foreign Component & Disclosures

What constitutes a Foreign Component: Prior approval for Foreign Components: Other Disclosure Requirements

The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended

Foreign Component: NIH Definition

*The performance of any **significant** scientific element or segment of a project **outside of the United States**, either by the recipient or by a researcher employed by a foreign organization, **whether or not grant funds are expended***

Foreign Component: NIH Definition

2-Step Process

Step 1: Will activities or intellectual contributions in support of the UCLA PI's NIH funded project be performed outside the US?

NO

No Foreign Component

YES

Move to Step 2 to determine if the activities are 'Significant'

Step 2: Significance

If the answer to **any** of the listed questions is **yes**, then there is a Foreign Component

Will the foreign activity or contribution involve human subjects or animals subjects?

Will there be extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities?

Will any activity of the project have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country?

Will the contribution or activity abroad include direct and significant intellectual contributions to design, conduct or analysis of research in pursuit of specific aims included in the NIH proposal or RPPR?

Will the contribution or activity abroad be considered fundamental or essential to the completion of the proposed aims/scope of work on a specific NIH funded project?

Prior Approval

NIH Foreign Component

The inclusion or addition of a Foreign Component to a NIH funded project requires NIH Prior Approval BEFORE the activity or collaboration begins

Obtaining Prior Approval for a Foreign Component

Disclosure in the proposal application

Subsequent addition requires a Prior Approval request

Example 1

The UCLA PI of a NIH-funded grant has a collaborator outside the U.S. who performs experiments in support of the PI's NIH-funded project, but there is no subaward of NIH funds from UCLA to the foreign collaborator.

Foreign Component

- ✓ Outside of USA.
- ✓ Performing experiments in support of the NIH project.
- ✓ NIH definition does not require grant funds to be expended for a foreign component to exist.

Reportable as Other Support?

- ✓ If it supports the current project, it should be included as part of the Facilities and Other Resources or Equipment section of the application. It is not reportable as Other Support for this project.
- ✓ It should be included as an in-kind contribution in Other Support (C&P) for reporting the PI must do for any other projects that don't directly benefit from the activity.

Example 2

A UCLA PI with an active NIH funded research project plans on taking a four-month sabbatical. He will be based in Italy while on sabbatical. Is this a foreign component requiring NIH prior approval?

Yes?

No?

Is the PI going to spend most of the time in Italy collecting data or samples pertinent to the NIH project?

Is the PI going to be working with collaborators at an Italian research institution on activities directly related to the NIH project, using their facilities and equipment?

Will the activity abroad include direct and significant intellectual contributions to design, conduct or analysis of research in pursuit of specific aims included in the NIH proposal or RPPR?

Is the PI not going to work on the NIH research while in Italy? If so, is prior approval for a reduction in effort required?

Is the PI going to discuss potential future research opportunities with colleagues at an Italian research entity?



Example 3

A NIH funded UCLA PI has a visiting postdoctoral fellow (a UK citizen) from the University of Oxford (United Kingdom) in her lab. The fellow performs research activities on the NIH funded project while doing all his work at UCLA. The fellow's salary is paid for by the University of Oxford.

Foreign Component?

- If all the fellow's work on the NIH project is being conducted in the US, there is **no** foreign component.

Reportable as Other Support?

- If the post-doc is performing research activities in support of the UCLA PI's research endeavors, then the postdoc's salary support funded by an external entity must be reported by the UCLA PI in her Other Support as an in-kind resource.

Example 4

A UCLA PI has a NIH grant received through UCLA. The PI also has an appointment and a lab at a university in Singapore. The research being done at the Singapore lab is unrelated to the PI's NIH project.

Does this qualify as foreign component?

- No, the foreign work is not part of the NIH-funded project. BUT....

Does it require UCLA Prior Approval?

- Yes, it's an APM 025 [Category 1](#) activity requiring an OATS disclosure and prior approval.
- There may be additional internal COI / COC considerations.

Is it reportable as in-kind Other Support?

- Yes, because it is a resource made available to the researcher in support of their research endeavors, but not directly supporting the NIH project.
- An English translation of the contract between the PI and the foreign institution must be included at JIT (or afterwards if the appointment occurs after the NIH award is made).

Should it be referenced in his bio-sketch?

- Yes, it's an affiliation or appointment with a foreign entity.

Key Take Aways: Foreign Component

- **Prior NIH approval is always required before work can start on a foreign component.**
- **Even if a foreign collaborator is not funded by NIH, prior approval by NIH may still be required. This will depend on:**
 - The geographic location of where an element / segment of the work is being performed, and
 - The 'significance' of the work to the NIH supported project.
- **A foreign component does not need to involve a foreign collaborator. The threshold can be met if:**
 - The NIH funded project involves extensive foreign travel by UCLA project staff for the purpose of data collection, surveying, sampling, and similar activities, or
 - If significant intellectual contribution to project aims are being conducted at a foreign location (for example when a PI is on sabbatical but is maintaining effort on research projects).
- **A foreign national performing work on NIH funded activities at UCLA is not a foreign component.**
 - However, depending on how their salary is funded, there may be an Other Support reporting requirement.
- **A foreign component may, but does not have to, involve a subaward to the foreign entity / collaborator.**
- **Inclusion of a future foreign component in an RPPR is an opportunity to obtain approval.**

Key Take Aways: Other Disclosures

- Reviewing whether a foreign activity meets the threshold for Foreign Component is a good opportunity to also consider the foreign activity in relation to other internal and external approval, disclosure, and reporting requirements.
- **Generally, (non-fCOI) disclosure requirements will be fulfilled if a Foreign Component:**
 - ✓ Has received NIH prior approval, and
 - ✓ Is underscored by a UCLA subaward agreement flowing NIH funds to the foreign subawardee (including data sharing and review obligations- see next section), and
 - ✓ The NIH funded project is included in the UCLA PIs Other Support reporting.
- **If a foreign activity or funding does not meet the threshold for Foreign Component there may still be internal and / or external mandatory prior approval and disclosure requirements. The extent of the approvals and disclosures will depend upon the nature of the activity / funding but could include:**
 - Internal UCLA review and approval such as [APM 025](#) Category 1 activity or an approved exception from [UCLA Policy 909: Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University](#) allowing the PI to submit proposals through an entity other than UCLA.
 - External reporting in Bio sketches, Other (Current & Pending) Support, including in-kind contribution reporting.
- **Always check disclosures for consistency and completeness. For example, if the PI reports external employment or a foreign (or domestic) research appointment or affiliation with another entity, it will need to be reported in the PI's biosketch and will likely need to be included as an in-kind contribution in Other Support.**
- Reach out to OCGA leadership if you have questions.

Resources: NIH Foreign Component & Other Disclosures

- **UCLA Resources**
 - OCGA [Other Support](#) webpages
 - [UCLA Policy 909](#)
 - [UC APM 025](#)
- **NIH Resources**
 - [NOT- OD-19-114](#)
 - [Frequently Asked Questions \(FAQs\) | grants.nih.gov](#)
 - [NIH Disclosures Table \(June 2, 2022\)](#)
 - NIH GPS
 - [Foreign Component Definition](#)
 - [Prior Approval Requirement](#)



NIH International Subawards

New Requirements

Process Overview & Resources

Prior Approval for NIH Subawards

Reminder

(Unlike most other sponsors) if a subaward was not included in the original NIH proposal, we generally do not need to request prior approval from NIH to add one later unless:

- Adding the subaward indicates a potential change in scope, OR
- The proposed subawardee is an international entity

NIH International Subawards New Requirements

Enhanced monitoring, documentation and reporting requirements for NIH subawards to international entities, effective January 1, 2024.

UCLA PIs need to ensure they have continued access to their international subrecipient's lab notebooks, data and documentation supporting the research outcomes described in Research Performance Progress Reports (RPPR) submitted to NIH. Access may be electronic.

Proposal Stage

NIH International Subawards

- UCLA's subrecipient **Letter of Intent (LOI)** has been updated to include a section for the international subrecipient institution's confirmation of the new NIH policy
 - Before submitting to OCGA, please be sure this section is completed if applicable.
- In addition, NIH expects **Letters of Support** from the international subrecipient PI acknowledging awareness of, and agreement to comply with, the requirement. 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.

Subaward Initiation

NIH International Subawards

- Submit required paperwork to OCGA OST, including the [OCGA Subaward checklist](#).
- On page 2 of the checklist, be sure to complete the (new) section titled: NIH International Subrecipient Data Collection requirement.

NIH International Subrecipient Data Collection Requirement *(This section to be completed for international subawards under NIH funding.)*

This is a request to issue a subaward to an international subrecipient under NIH funding. The UCLA Principal Investigator (UCLA PI) for this project is aware that subaward agreements to foreign subrecipients will include a NIH award term requiring all foreign subrecipients to provide the UCLA PI "access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report...no less than once per year" and that the UCLA PI will be responsible for collecting, documenting receipt of, reviewing and ensuring access to the above and retaining it for three years after submitting the final financial report (in accordance with NIH NOT-OD-23-182).

*UCLA guidance regarding NOT-OD-23-182 requirements and process recommendations can be found at:
<https://ocga.research.ucla.edu/wp-content/uploads/UCLA-OCGA-Guidance-NIH-Data-Collection.pdf>*

- OCGA OST will add terms to the subaward agreement requiring that the subawardee provide access to data and records, but without going into the specific details of how that will occur.

Subaward Initiation

NIH International Subawards

- ❑ ‘When, what and how’ details related to support documentation should be agreed between the UCLA PI and the subawardee PI **before the international subawardee efforts commence** .
- ❑ A list of considerations the UCLA PI may want to discuss and agree with the subawardee PI is available on the [OCGA OST webpages](#).
- ❑ UCLA PI should document details of the ‘when, what and how’ agreement and share it with the subaward PI (e.g., email confirmation between PIs).
- ❑ UCLA must put a plan in place to retain access to the documentation throughout the life of the award and for three years after the submission of the final financial report.

Guidance for PI Review of Research Records of International Subawardee

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?
- Are there any third-party data licensing requirements?
- Will files include personally identifiable information (PII)?
- PII may need to be removed and information de-identified prior to sharing.
- 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?
- How will the UCLA PI document review of the subawardee's research records?

After Subaward Setup



Confirm setup of the data repository



Confirm access to data



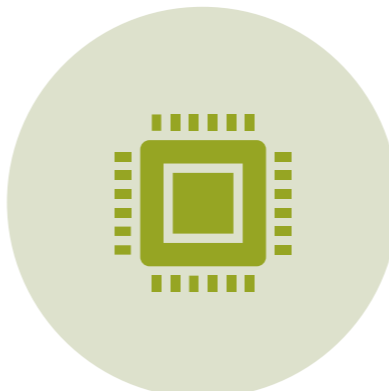
Review data at least annually to confirm that it is properly reflected in the RPPR. **Every time the UCLA PI reviews the records, they should document the review.**



NIH will require 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 on UCLA servers for at least 3 years following submission of the project's final financial report to NIH

Resources: NIH Funded International Subawards

- **OCGA / OST Resources**
 - [UCLA Guidance on NIH Foreign Subawards](#)
 - [Subrecipient LOI](#)
 - [Subaward Checklist](#)
- **NIH Resources**
 - 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-nihs-foreign-subaward-agreement-policy-addressing-community-feedback/>

Other Updates

Uniform Guidance

Timeline for Updates?

Pushed back until October 2024

Proposed changes include:

- Increasing subaward MTDC threshold from \$25,000 to \$50,000
- Increasing equipment threshold from \$5,000 to \$10,000
- Increasing de minimis F&A rate for a subawardee from 10% to 15%

NIH

GPS March 2024

Roll out of Common Disclosure forms delayed until January 2025

SciENCv target May 2025

NSF PAPPG

Effective May 2024

All senior / key personnel must certify that they are not a party to a Malign Foreign Government Talent Program (MFGTP)

[MFGTP definition](#)

OCGA Monthly Training

Completing the EPASS

March 20 @ 9:30am

Electronic EPASS System

March 27 @ 9am

[Registration](#)