Other Support, Foreign Influence, & RSS

Charles Maris, PhD Assistant Director, Sponsored Programs Administration



1

Agenda

V

- 1. A recent Change: Foreign Subrecipients
 - The regulation
 - How it impacts you and SPA's K Team
- 2. Foreign Influence
 - Background
 - The road ahead
- 3. Other Support
 - Who is asking for it?
 - What is it?
 - Why do we need it?
 - Who does which work and when?

NIH Updated Policy Guidance for Subaward/Consortium Written Agreements
Note Number.
NOT-00-23-133
Key Dates

Effective Date: Octo

lease Date: May 15

Related Announcements

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

This notice updates the NIH Grants Policy Statement (NIHGPS), Section 15.2, which outlines the requirements for conscribing subsected agreements on NIH-funded grants. These updates will be incorporated into the GPS in the FY24 publication. This updated guidance is effective October 1, 2023. A Federal Register Notice amounting the updates will be posted in the coming

2 CPR2.00.25(3)(5)(5) states that substance designerer may relate from the subsequence present the passed frough entity and auditors to have access to the exception of the passed frough entity and auditors to have access to the exception of the passed from the passed frough entity and auditors to have access to the exception of the passed from the

Administrative

V

SPA Office Hours are ending in August (last one is **tomorrow**)

Thank you to those of you who joined us!

We will be rolling out new training sessions and developing improved ways of communicating with campus colleagues this Fall.

Stay tuned!



3

NIH Updated Policy Guidance for Subaward/Consortium Written Agreements

U

NOT-OD-23-133

- This notice updates ... the requirements for consortium/subaward agreements to foreign subrecipients on NIH-funded grants.
- These updates will be incorporated into the GPS in the FY24 publication.
- This updated guidance is effective October 1, 2023.
- A Federal Register Notice announcing the updates will be posted in the coming weeks (the comment period is now open.)

NOT-OD-23-133

Current state: 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."

...NIH has determined that to assure that this requirement is met, NIH finds it necessary to impose a requirement that foreign subrecipients turn over **all records** to the primary recipient at an agreed upon frequency (e.g., once a quarter, once a month).



5

NOT-OD-23-133: updates 1

NIH will not support any agreement that does not meet the minimum requirements outlined in the written agreement section below (15.2.1/next slides). NIH reserves the right to request copies of the written agreement and relevant supporting documentation as needed, as part of its oversight responsibilities. Failure to provide requested documentation may lead to remedies for noncompliance and potential enforcement actions.



NOT-OD-23-133: updates 2

NIH encourages recipients to ask potential subrecipients, at the application stage, to submit language in their letters of support indicating their awareness of these requirements and the subrecipient's willingness to abide by all requirements should an award be issued.



Let's do our best to set expectations early, such as in our LOIs.

7

NOT-OD-23-133: updates 3

Note that this requirement does not apply to *vendors*

Criteria	Subaward	Vendor	Consultant
Is it considered a federal award?	Yes	No- It is a payment for goods & services	No-It is a payment for a service
Performance measured against objectives of Federal Program?	Yes	No	No
Responsible for programmatic decision making?	Yes	No	No
Must adhere to applicable Federal program compliance requirements?	Yes	No	No
Subject to audit under A- 133?	Yes	No	No
Mechanism	Subagreement	Purchase Order	Consulting Contract

Only for subrecipients (a collaboration between scientific co-equals with intellectual contributions coming from both parties and the expectation to publish jointly, IP rights shared, etc.

NOT-OD-23-133: The Written Agreement

The recipient must enter into a formal written agreement, signed, and agreed to by both parties, with each consortium participant/subrecipient that addresses the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements of the grant, including those necessary to ensure compliance with all applicable Federal regulations and policies and facilitate an efficient collaborative venture. If a subrecipient is unwilling to accept the requirements outlined in this section, by

signing a written agreement, then an agreement cannot be issued.

Bold parts are new Orange is me

9

The written agreement (subaward) must include...



*Identification of the individual who will serve as the consortium lead investigator and other individuals responsible for the research activity at each consortium participant along with their roles and responsibilities.

*Identification of the individuals holding the policy of the price of

чисму гониво и из выпосырентя work for the prime institution.

If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the written agreement shall specify time period(s) for the subrecipient to report all identified Financial Conflicts of Interest to the prime Institution. Such time period(s) shall be sufficient to enable the prime Institution to provide timely FCOI reports, as necessary, to the PHS as required by the regulation.

timely FCOI reports, as necessary, to the PHS as required by the regulation.

*Alternatively, if the subrecipients investigators must comply with the prime institutions. Financial Conflict of Interest policy, the written agreement shall specify time periods; bride subrecipients investigator disclosures of Significant Financial Interests to the prime institution. Such time periods; shall be sufficient to enable the prime institution to comply timely with the review, management, and reporting obligations under the 2011 reviewed FCOI regulation.

*A provision addressing ownership and disposition of data produced under the cornerment. This includes whether cell lines, samples or other resources will be reviewed to other resources in the prime institution to other the progress report the services of the progress report. The support of the progress report. These supports in the review of the progress report. These supports prime are provided to prime recipient with each scientific update (no less than once every three months) in line with the timelines outlined in the agreement.

*A provision making NIH data sharing and inventions and patent policy, including a requirement to profit in the recipient special progress of all supports in the recipient special property. A provision for activities of the progress requirement of propertive profit in the recipient of the recipient special property. The progress requirement of provided to prime recipient with each scientific update (no less than once every three months) in line with the timelines outlined in the agreement.

**A provision making NIH data sharing and inventions and patent policy, including a requirement to profit inventions to the recipient (see Administrative Requirements-Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources in IIA), applicable to each consortium participant and its employees in order to ensure that the religion is to the profit of the profit is the time intellectual property), program in

Provisions regarding compliance with requirements for a UEI and subrecipient reporting under FFATA (see Recipient Reporting of Subrecipient Data and Executive Compensation Information for FFATA). Note, the recipient must provide the FAIN to all subrecipients to aid in this requirement.

Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates in IIA).

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-133.html

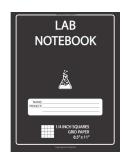
Let's zoom in



New part

The written agreement (subaward) must include

For foreign subrecipients, a provision requiring the foreign subrecipient to provide copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report. These supporting materials must be provided to prime recipient with each scientific update (no less than once every three months) in line with the timelines outlined in the agreement.



https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-133.html

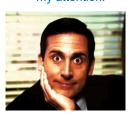
11

NIH is listening and clarifying, with more to come

https://www.niaid.nih.gov/grants-contracts/october-changes-subawards-foreign-subrecipients

- NIH grant recipients may make subawards such that another organization performs certain grant-supported research
 activities as part of the federal award.
- Subawards are also called consortium agreements. Transactions such as normal grant purchases and fee-for-service
 arrangements are not considered subawards.
- Notably, NIAID [NIH] does not interact with subrecipients.
 - Grant recipients are accountable for arranging the subrecipient's research, spending, and reporting actions, which
 must conform to all terms and conditions of a grant award.
 - If a dispute arises between a grant recipient and a subrecipient, [NIH] is not responsible for resolving the matter.
- NIH published a corresponding notice in the Federal Register, which includes a call for public feedback on the requirement
 that foreign subrecipients turn over records to the grant recipient at routine intervals. You can submit a response ... the
 deadline is July 5, 2023, at 11:59 p.m. Eastern Time.
- · We will publish additional, practical instructions in this newsletter as they become available.

They have my attention!



To summarize the October changes

- Subawards must be formalized by a written agreement and the document must signed by both parties. The
 agreement should address negotiated arrangements for fulfilling the grant award's scientific, administrative, financial,
 and reporting requirements.
 - If the subrecipient is unwilling to sign such a written agreement, then the grant recipient cannot make the subaward.
- 2. For a foreign subrecipient, the written agreement must stipulate that the subrecipient will provide copies of all lab notebooks, data, and documentation that support the research outcomes as described in the progress report.
 - These supporting materials must be provided to the grant recipient with each scientific update (no less than once every 3 months).
- 3. If you arrange a subaward while preparing a grant application, instruct the potential subrecipient to include language in the corresponding letter of support that demonstrates awareness of all applicable grant requirements and willingness to abide by them should an award be made.
- 4. NIH reserves the right to request copies of the written agreement and relevant supporting documentation as needed, as part of its oversight responsibilities. Failure to provide requested documentation may lead to remedies for noncompliance and potential enforcement actions.

13

How will this impact your applications with foreign subrecipients?



- We intend to comply.
- We will apprise our foreign collaborators of the new requirement (they know).
- We will ask our foreign subrecipients to include appropriate language in their LOIs.
- We will monitor <u>www.thefdp.org</u> for templates, suggestions, and guidance.
- We will examine institutional and SPA policy, and will communicate further, across campus.



How did we arrive here?

There have been some interesting high-profile lapses with international subrecipients that likely contributed to the new requirements.





It's fun to guess and discuss, but what matters now is *studying* (the regs), *listening* to our colleagues (FDP and others), *watching* for further NIH guidance, and *focusing on implementation*.

15

The comment period is open



Once the comment period is closed, we will be able to see other institutions' approaches and concerns related to this significant change.

What we know we know

NIH updated Other Support Requirements Jan 25, 2022

- Formatting changes to highlight in-kind contributions
- Requirement to collect Sr/KP contracts/agreements re: foreign appointments and/or employment
- · Immediate notification of undisclosed Other Support
- · PI signatures on OS

Foreign Talent/Recruitment Programs: they have come, but have they gone?

Critical technology trackers paint a stark picture.

https://www.aspi.org.au/report/critical-technology-tracker



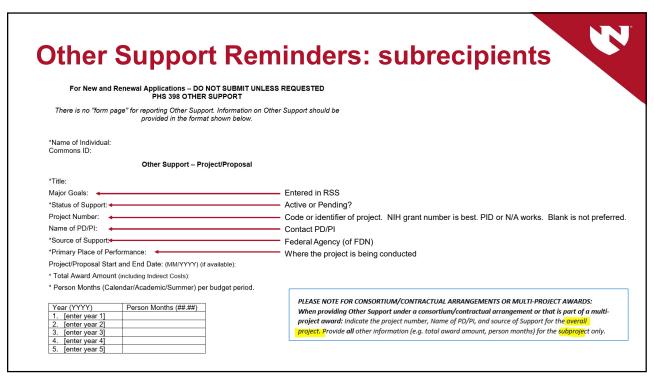
17

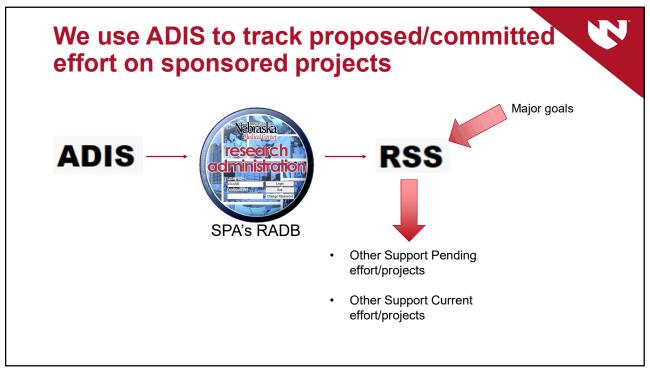
Other Support Reminders

There is an NIH kiosk: https://grants.nih.gov/grants/forms/othersupport.htm

- It is excellent.
- Instructions
- Policy
- Templates
- Examples
- Guidance on what to report
- FAQs







A quick knowledge check, and discussion

21

Q&A



I am the PI on a NIH grant to a domestic university. I have a visiting post-doctoral fellow in my lab, who works on my NIH grant and does all of his/her work in the United States. The fellow's salary is paid by a foreign government. Is this a foreign component?

In general, no. The first step in determining whether research constitutes a foreign component is to evaluate whether a portion of the research is being conducted outside of the United States. In this case, all of the work is being conducted in the US, so there is no foreign component.

https://www.niaid.nih.gov/grants-contracts/fast-facts-about-foreign-components



I am a PI on an NIH award to a domestic university. I will have a visiting fellow joining my lab whose salary will be supported by a foreign university. Do I need NIH prior approval before the fellow can work on my NIH funded research?

Since specific circumstances may vary, it would be best to discuss with your Grants Management Officer. (They will say "yes.")

https://grants.nih.gov/faqs#/search/635/subrecipient

23

Q&A



If an institution identifies a resource that was not reported in Just-in-Time or at the time of the RPPR, how should the institution notify NIH?

And when?

If an organization discovers that a PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information outside of Just-in-Time or the RPPR, as applicable, the institution must submit updated Other Support to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.

https://grants.nih.gov/grants/forms/othersupport.htm

https://grants.nih.gov/faqs#/search/635/subrecipient



Do researchers report gifts in Other Support?

No, gifts should not be reported in Other Support. Reminder, gifts are resources provided where there is no expectation of anything (e.g., time, services, specific research activities, money, etc.) in return.

https://grants.nih.gov/grants/forms/othersupport.htm

https://grants.nih.gov/faqs#/search/635/subrecipient

25

Q&A



Should the dollar amounts reflected on the Other Support document reflect annual total cost or annual direct cost only?

Other Support submissions should provide the total award amount, direct and indirect, for the entire project period (e.g. competitive segment for NIH grants), not just the annual budget period.

http://grants.nih.gov/sites/default/files/nih-other-support-instructions-rev-06-28-2021.docx



When a researcher is including information on a subproject in Other Support, should the researcher provide the total award amount for the overall award, or only the subproject?

For subprojects, recipients should provide the project number and PD/PI name for the overall project. All other information, including total award amount and person months, for the subproject only. http://grants.nih.gov/sites/default/files/nih-other-support-instructions-rev-06-28-2021.docx

https://grants.nih.gov/faqs#/search/635/subrecipient

27

Q&A



When a researcher works on a subaward to an NIH grant that is awarded to another institution, how should that information be included in Other Support?

The researcher should provide the project number, PD/PI name for the prime award. All other information, including the total award amount and person months, should be specific the subaward.

http://grants.nih.gov/sites/default/files/nih-other-support-instructions-rev-06-28-2021.docx



If a PD/PI or other senior/key personnel is mentoring post-doc or graduate students who are individually funded through an outside institution) e.g. foundation or home university), does that need to be disclosed as an in-kind resource in Other Support?

If the post-doc or graduate student is performing research activities in support of the PD/PI or other senior/key personnel's research endeavors, then their support must be reported as an in-kind resource. If the relationship is solely a mentor/mentee arrangement, with no research activities performed by the mentee and no associated time commitment by the mentor, then it is not a resource and does not need to be reported.

https://grants.nih.gov/faqs#/search/635/subrecipient

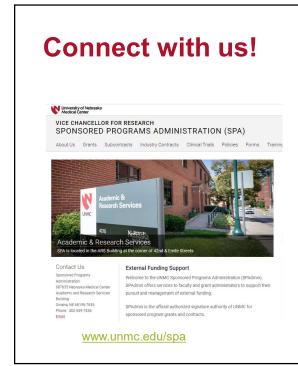
29

Q&A



What should I do if I'm not sure if something needs to be included as Other Support?

In the interest of full transparency, recipients should err on the side of disclosure. Researchers should consult with their institutional officials for guidance to ensure compliance with institutional and NIH policies. NIH requires complete and accurate reporting of all sources of research support, financial interests and affiliations, both foreign and domestic.



Charles Maris, PhD Assistant Director Sponsored Programs Administration cmaris@unmc.edu

31

