

UC San Diego

Health Sciences

**NIH UPDATES MEETING (HS CONTACTS)
SEPTEMBER 27, 2023**

Rachel Cook, Interim Director, Health Sciences Projects Pre-Award Office (HS SPPO)



Agenda

NIH Updates & Reminders

- Updated NIH Application Instructions: Data Management and Sharing (DMS) Costs
- NIH Final Policy Guidance for Subaward/Consortium Written Agreements
- Loan Repayment Program (LRP) Applications Are Open!
- Other Support & Flattening DocuSign PDFs

UC San Diego/Health Sciences Updates & Reminders

- HS SPPO is coming back to campus
- UCSD Subaward/Consortium AO & SO Contacts
- IACUC & IRB Protocol Approvals
- Kualii PD Record and/or eRA Commons & ASSIST

NIH UPDATES & REMINDERS

NOT-OD-23-161: NIH Application Instruction Updates – Data Management and Sharing (DMS) Costs for “Research” Applications

NIH has walked back on the required single line item for, under F. Other Direct Costs for research applications due on or after October 5, 2023. Now, you go back to how it was done prior to January 25, 2023, in that you request were costs occur in the Detailed Budget, regardless of if the cost is personnel or non-personnel DMS costs.

However, you will continue to call out costs in the justifications, with a sub-heading (label) named “Data Management and Sharing Costs,” followed by the estimated dollar amount (total direct costs). If no cost will be incurred, enter "0" for the estimated dollar amount.

Additionally, you should include a brief justification of the proposed activities that will incur DMS costs.

- Provide a brief summary of type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared.
- Indicate general cost categories such as curating data and developing supporting documentation, local data management considerations, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation.
- The recommended length of the justification should be no more than half a page.

Updated SF424 Guidelines:

- [Detailed Budget & Detailed Budget Justification](#)
- [Modular Budget Additional Justification](#)

NOT-OD-23-182: NIH Final Updated Policy Guidance for Subaward/ Consortium Written Agreements

NIH has stressed this is not a new policy, but another clarification/update to an already current policy. This update is in response to audits conducted by the HHS Office of the Inspector General and the Government Accountability Office.

This final updated policy will require that foreign subrecipients provide 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 no less than once every six months.

*UCOP RPAC and the UC campuses started discussions last week to discuss how this will affect research and our NIH-funded PIs. Once more has been determined as well as any local policies or guidelines, we will pass this information on to you all.

NOT-OD-23-182: NIH Final Updated Policy Guidance for Subaward/ Consortium Written Agreements

Effective January 1, 2024, §15.2 will be updated to include the following clarifications (changes are **bold** and *italicized*).

15.2 ADMINISTRATIVE AND OTHER REQUIREMENTS

- The following highlights several areas within the consortium relationship that the recipient needs to address with consortium organizations receiving subawards under a grant to ensure compliance with NIH requirements. The requirement for a written agreement addressing these and other areas is specified in this section. ***NIH will not support any agreement that does not meet the minimum requirements outlined in the written agreement section below (15.2.1). 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 (see 8.5, Specific award conditions and remedies for noncompliance).***
- ***NIH expects 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.***
- Note that most of these requirements only apply to a recipient's consortium relationships with sub-recipients. When the relationship is with a vendor that is providing routine goods and services within normal business operations that are ancillary to the operation of the research program, the public policy requirements listed below do not apply. The vendor must also be providing similar goods and services to many different purchasers and provide them in a competitive environment.

NOT-OD-23-182: NIH Final Updated Policy Guidance for Subaward/ Consortium Written Agreements

15.2.1 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.*** At a minimum, this agreement must include the following:
 - Note: All current requirements remain in place, with the addition of:
 - ***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.***

NOT-OD-23-182: NIH Final Updated Policy Guidance for Subaward/ Consortium Written Agreements

For existing foreign subaward agreements established prior to January 1, 2024, NIH expects recipients to update existing foreign subaward agreements within 60 days of the effective date to address the requirements outlined in NOT-OD-23-182

Resources

- [Subaward Page](#)
- [Subaward FAQs](#)
- [Good Article: Research Security: New NIH Policy Requires Foreign Subrecipients to Share Lab Notebooks and Research Data with the US Prime Awardee](#)

NIH Webinar on Subaward Requirements: Domestic and Foreign



- Tuesday, October 17, 2023: 10:00-11:00 AM PT (1:00-2:00 PM ET)
- Join experts from the NIH Office of Policy for Extramural Research Administration (OPERA) for a walk-through of subaward agreements. Gain insight, ask questions, and learn about key policy requirements during this informative and engaging virtual event.
- What are the components of a subaward agreement?
- What are key policy requirements?
- Register for FREE [here!](https://grants.nih.gov/learning-center/nih-subaward-requirements)

Loan Repayment Program (LRP) Applications Are Open!

NIH will repay up to \$50,000 annually of a researcher's qualified educational debt in return for a commitment to engage in NIH mission-relevant research. These awards are eligible for competitive renewals. For more information, see this recent [Open Mike Blog](#) on the program or the link below.

The current FY 2024 application cycle for LRPs closes on November 16, 2023.

If you are in HS, please contact [Elizabeth Tang](#) and let her know your plans to submit an application as well as select her as your IBO in ASSIST. No Quali PD Record is required!

<https://www.lrp.nih.gov/>



Other Support & Flattening Electronically Signed PDFs

When submitting Other Support or other documents that require a signature, often more than one attachment needs to be combined into the file. When combining adobe pdf files with DocuSign signatures you must make sure the file is a “flattened pdf”, not a fillable form.

There are two ways to flatten a PDF:

- You can flatten the file by “printing” in adobe to “pdf,” then combine the “printed” pdf attachments. This will resolve the signatures disappearing from the combined attachment.
- Or you can *Drag & Drop* into an open Browser window. This will open the PDF up in the browser, allowing you to *Print to PDF*. This will remove all security features and all you to combine PDFs as well as allow you to upload the unsecured/flattened PDFs into eRA Commons or your ASSIST application. Another variation on the *Drag & Drop* is to right-click on the file and request to open it with your browser, then *Print to PDF*.

Possible Government Shutdown & NIH

With a looming government shutdown, you might start to get answers from your PIs on if the 10/5 deadline will still be “on” or if it will be delayed.

The last big government shutdown, the 10/5 deadline was still “on” and we were submitting without issues. However, the Peer Review meeting were postponed, which led to longer start dates on pending applications. Additionally, there is no guarantee the helpdesks will be staffed for grants.gov or eRA Commons at this time.

For more information on possible government shutdown, please go to [UCOP RPAC's website](#).



UC San Diego

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HEALTH SCIENCES SPECIFIC UPDATES/REMINDERS



HS SPPO is Coming Back to Campus!

Some of us at HS SPPO will be returning to campus in October. We will be here from 1-3 days, with others coming in intermittingly.

We will be located over on East Campus, at the ACTRI Building, 2nd Floor East.

We will be available for face-to-face meetings as well as requested 1:1 training.

UCSD Subaward/Consortium AO & SO Contacts

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- 12. Administrative Official (AO) should be Stella Sung's name and OCGA's main #. The email should be ucsdawards@ucsd.edu. Please stop using researchadmin@ucsd.edu.
- 13. Signing Official (SO) should be your HS SPPO C&G Officer's name and title. The Telephone # should be our main # 858-822-4109. The email should be vchsgrants@health.ucsd.edu.

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- 3b. Telephone # should be the general # for OCGA.
- 5. The Administrative Official (AO) should be Stella Sung's name and OCGA's main #. The email should be ucsdawards@ucsd.edu.
- 11. Signing Official (SO) should be your HS SPPO C&G Officer's name and title. The Telephone # should be our main # 858-822-4109. The email should be vchsgrants@health.ucsd.edu.

Subrecipient Commitment Forms

- The same as above. The AO should be Stella Sung and the email should be ucsdawards@ucsd.edu and the SO should be your HS SPPO C&G Officer and the email should be vchsgrants@health.ucsd.edu.

IACUC Protocol Approvals

Do NOT send directly to NIH or upload to eRA Commons JIT or ASSIST Revision Applications the IACUC Protocol Approval Letters. Instead, either email HS SPPO the protocol approval #s or add the protocol approval # to the Kualu PD Record (if a Revision application or Non-SNAP RPPR).

JIT & Revision Applications: HS SPPO routes the application and protocol # to the IACUC office for a congruency review.

- **JIT Stage:** Once HS SPPO Receives the approval, then we will upload the approval date into eRA Commons.
- **Revision Application:** Once HS SPPO receives the approval, then we will upload a signed letter with the applicable IACUC information.

Non-Competing Progress Reports (Non-SNAP RPPR): HS SPPO verifies in the IACUC system that the protocol is still approved and will be approved beyond the start date of the next budget cycle.

IRB Protocol Approvals

As with IACUC, do NOT send directly to NIH or upload to eRA Commons JIT or ASSIST Revision Applications the IRB Protocol Approval Letters. Instead, either email HS SPPO the protocol approval #s or add the protocol approval # to the Kualu PD Record (if a Revision application or Non-SNAP RPPR).

JIT & Revision Applications: HS SPPO requests a PI Attestation to the protocol matching the science proposed in either the pending application (*done at time of JIT*), including revision (*done at time of submission*)

- **JIT Stage:** Once HS SPPO Receives the approval (via email), then we will upload the approval date into eRA Commons.
- **Revision Application:** Once HS SPPO receives the protocol #, then we will upload the signed Form 0990-0263: Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule), with the IRB protocol approval information.

Non-Competing Progress Reports (Non-SNAP RPPR): HS SPPO verifies in the Kualu IRB system that the protocol is still approved and will be approved beyond the start date of the next budget cycle. Note, a PI Attestation will be required in the Kualu PD Record.

Kuali PD Record and/or eRA Commons & ASSIST

What is an Internal Deadline vs Hard Deadline?

HS SPPO considers an **Internal Deadline** to be for awards that are already here at UCSD, but have no corresponding Kuali PD Record. **Hard Deadlines** should be all other pending applications or progress reports with hard deadlines. If we are a subaward, then we request you put the requested deadline date for the institution submitting to NIH.

When Would You See Academic & Administrative Approvers and Why are They Crucial to Your Application?

A **HARD STOP** on your Kuali PD Record means that either there is new space, a PIE is required*, or there is cost share. These three instances require additional approvals from your academic and administrative approvers. It will not route or re-route to HS SPPO until both parties have approved the record. If it is not in HS SPPO's stop, then we can not submit the application or progress report.

Do not “protect”, “read-only”, add rules, passwords or any security in any attachments. Including internal budgets. It makes it impossible for us to work with the document.

- If in ASSIST, we will not be able to open the document for review. Moreover, if we cannot open it, then it will cause an error upon submission. The need to be flattened PDFs.
- If in Kuali PD Record, it is also difficult to open and review. Please make sure all secure features have been removed and the file is easily opened.

*PIEs also require a PIE that at time of submission requires the PIE to be signed by the PI and approved by the Chair.

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