HS SPPO Contacts Meeting
September 14, 2022
Agenda

UC San Diego & HS SPPO Updates & Reminders
• HS SPPO Interim Director & 2 New Analysts
• Updated Staff Assignments
• Updated Review Priorities Posted on HS SPPO Website
• Update on Reviews Moving HS ServiceNow
• Note on OCGA’s Dashboard
• Reminder on Subs and/or Internal Applications
  • Minimum Requirements for Review
  • Types of Attachments Uploaded
• Reminder on IRB Attestations
• Reminder of Hard Stops in PD
• Reminder of When a Salary Waiver is Required

NIH Updates & Reminders
• Sign Up for the Virtual NIH Grants Conference and PreCon Events Today!!!
• Grants.Gov is Migrating to the Cloud…and will be down
• Reminder: Change is Coming to Data Sharing in Applications + Forms H will be here Soon!!!
• Reminder: Clarifying Digital e-Signatures for Other Support & How to Flatten a Secure PDF
• Reminder: Clinical Trials ct.gov # must be included in RPPRs
UC San Diego & HS SPPO Updates/Reminders
HS SPPO Interim Director & 2 New HS SPPO Analysts

Interim Director, Rachel Cook
Sr. Grant Analyst, Angela Vivola
Grant Analyst, Nicole Ketchum
## Updated Staff Assignments – Effective Monday, 9/19/2022

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<thead>
<tr>
<th>Rachel</th>
<th>Evelyn</th>
<th>Roxanne</th>
<th>Stella</th>
<th>Anastasia</th>
<th>Angela</th>
<th>Nicole</th>
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<tr>
<td>CTRI Moores Cancer Center Skaggs School of Pharmacy and Pharmaceutical Sciences</td>
<td>NIH LRP IBO</td>
<td>Medicine:  • Biomedical Informatics  • General Internal Medicine  • Pulmonary Psychiatry</td>
<td>CRBS Emergency Medicine  Medicine:  • AVC Translational Medicine  • Global Public Health  • Rheumatology  • Hematology and Oncology  • School of Medicine Administration Ophthalmology Pathology Pharmacology</td>
<td>Anesthesiology  CMM Medicine:  • AVC Translational Medicine  • Global Public Health  • Rheumatology  • Hematology and Oncology  • School of Medicine Administration Ophthalmology Pathology Pharmacology</td>
<td>Medicine:  • Endocrinology/Metabolism  • Cardiology  • Gastroenterology  • Infectious Diseases &amp; Owen Clinic Obstetrics, Gynecology, and Reproductive Sciences</td>
<td>Medicine:  • Nephrology Pediatrics</td>
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[https://medschool.ucsd.edu/vchs/research-services/hssppo/review/Pages/Analyst-Review-Assignments.aspx](https://medschool.ucsd.edu/vchs/research-services/hssppo/review/Pages/Analyst-Review-Assignments.aspx)
Updated Review Priorities Posted on HS SPPO Website

Review Priorities → What is reviewed/checked by the Department and by your HS SPPO Analyst

These are posted on the HS SPPO Website, under:

1. Review & Submission tab → click on Application Preparation, then click on either the
   • ASSIST option; Paper Submissions (Subawards) option; or Grant Transfers option.

2. Post-Submission tab, click on either the
   • Non-SNAP RPPRs option and Coming Soon: Just-in-time (JIT) option & Post-Submission Materials
     option.

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<tr>
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<th>Review Responsibility</th>
<th>Additional HSSPO Auditing</th>
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<td>HS SPPO</td>
<td>Depending on submission timeline, Ensures correct info, FOA, and form type (i.e. Forms G).</td>
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<td>1. Vertebrate Animal Section</td>
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<td>2. Program Income Section</td>
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<td>Department</td>
<td>Ensures completed properly</td>
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<tr>
<td>3. Human Embryonic Stem Cells Section</td>
<td>Department</td>
<td>Department</td>
<td>Ensures completed properly and compliance when applicable</td>
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Update on Reviews Moving HS ServiceNow & Note on OCGA’s Dashboard

- **HS SPPO Reviews**: In last month’s HS SPPO Newsletter, we mentioned the planned transition of our review workflows from OnBase to HS ServiceNow. It was expected that this would have been completed by the beginning of this month, but we have run into a couple of snags that have caused our transition to be delayed. Once we have more information on the official transition date, we will then announce the date as well as schedule trainings on how to use the new system to see your reviews as well as communicate with your HS SPPO Analyst in the system.

- **OCGA Dashboard**: Data on where HS SPPO is in their reviews does not show up on OCGA’s Dashboard. At this time, it does not communicate with OnBase or ServiceNow, thus it is only showing OCGA’s workflows.
Reminder on Subs and/or Internal Applications

**Minimum Requirements** for Review by HS SPPO for:

- When UC San Diego is the Applicant;
- When UC San Diego is the Subaward/Consortium to Another Institution Submitting to NIH;
- When a New UC San Diego PI is Transferring their Current NIH Awards from their Previous Institution to UC San Diego; or
- When a Professional Degree Graduate Student or Post Doc is submitting an F30 or F32 Fellowship Application to NIH.

- Our Minimum Requirements include what is required in the PD Record (including specific attachments) and what is required in either the ASSIST application or the Non-SNAP RPPR.

- All applications or Non-SNAP RPPRs that come into HS SPPO are audited by our front desk person. They are looking to make sure all minimum requirements have been met. If anything is missing, then they will send the PD Record back till all items have been correctly collected. Once this occurs, then the record is entered into OnBase and forwarded to the HS SPPO Analyst for review and eventual submission.
To submit your sub-award application to HS SPPO for review and/or submission, please follow the instructions for PD. HS SPPO requests that the Subaward Package be combined into ONE (1) PDF rather than uploaded as individual attachments for ease of use. However, if an SF424 Subaward Budget is included, please have this be a separate upload since the form is interactive. Do not print this to PDF to flatten and include in the Subaward Package. Moreover, do not create a PDF Portfolio that contains both the Subaward Package and the interactive SF424 Subaward Budget.

### When UC San Diego is the Subaward & Types of Attachments in PD

To submit your sub-award application to HS SPPO for review and/or submission, please follow the instructions for PD. HS SPPO requests that the Subaward Package be combined into ONE (1) PDF rather than uploaded as individual attachments for ease of use. However, if an SF424 Subaward Budget is included, please have this be a separate upload since the form is interactive. Do not print this to PDF to flatten and include in the Subaward Package. Moreover, do not create a PDF Portfolio that contains both the Subaward Package and the interactive SF424 Subaward Budget.

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<thead>
<tr>
<th>New/Renewal/Resubmission/Revision</th>
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<td><strong>•Attachments: Internal</strong></td>
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<td>PHS 2590 Progress Report Package (1 PDF)</td>
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<tr>
<td>SF424 Subaward Budget (Interactive PDF)</td>
<td>SF424 Subaward Budget (Interactive PDF)</td>
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<td>•PI Exception</td>
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<td>•Cost Share Documentation</td>
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[https://medschool.ucsd.edu/vchs/research-services/hssppo/review/application-prep/Pages/Paper-Submissions-Sub-awards.aspx](https://medschool.ucsd.edu/vchs/research-services/hssppo/review/application-prep/Pages/Paper-Submissions-Sub-awards.aspx)
Reminder: IRB Attestations for JIT/RPPRs/Supplement Applications

- The IRB Office no longer does congruency reviews for federal awards, such as NIH.
- The onus has shifted to the PI on whether or not the IRB protocol # is accurate.
- The PI must send an email to the HS SPPO Analyst (upon request) where they confirm the appropriate IRB Protocol #(s). Once HS SPPO has received the protocol #(s) and email, they can then verify the approval and dates in Kuali Protocols.

Email language is on our Resources webpage: "I confirm this IRB approval is associated with this application/grant/award. This protocol represents the research being performed in this application/grant/award."
Reminder of Hard Stops in PD & PIEs

When you are submitting a proposal (NIH or non-NIH) and the PI requires a PI Exception this is considered a “Hard Stop” for submission till two things have occurred:

1. The PI Exception has been fully completed and signed by the PI as well as approved and signed by the Department Chair and routed to HS SPPO for review; and

2. The PD Record has been submitted for review and approval by the Department DBO and Chair. Once both of these approvals are done, then the record will route to HS SPPO for either review or submission. Please note, when the record is sent back for corrections, this re-starts the approval routing process all over again. We cannot submit unless the record is fully approved.

NOTE: We have been having some issues with the PIE Form in OnBase. Please be patient and alert your HS SPPO Analyst to a PIE so they may assist you with any issues that may be occurring.
Per UC Policy, a PI must have measurable salary to effort on a proposal except for when the following situations are in place:

1. The funding agency does not allow PI salary;
2. The PI holds an HHMI or Ludwig appointment and is not allowed to budget salary;
3. The sponsoring agency (i.e. NIH, DOD, etc.) limits the annual award amount to less than $50,000; or
4. A salary waiver request has been processed and approved by the Director of HS SPPO.

Note: A Professor Emeritus can have up to 30% of effort without salary in a grant application without a salary waiver. This would not be considered cost-sharing.

Salary Waivers are allowed for up to 5% effort with salary. Anything above this and that % would be considered cost share. Moreover, this does not apply to Co-Investigators who are allowed up to 5% effort with no salary – and this is not deemed to be cost share.

Salary Waiver request template can be found here.

https://medschool.ucsd.edu/vchs/research-services/hssppo/review/Pages/SalaryEffort-Concerns.aspx
NIH Updates & Reminders
2022-2023 Virtual NIH Grants Conference and PreCon Events

Cost: **FREE!!!**
Watch **LIVE** or Watch **later on NIH Grants YouTube Channel**!

**Learn** about NIH grants policies!
**Interact** with NIH experts!
**Engage** and network with your peers!
**Gather** resources to use and share with colleagues!

**NIH Loan Repayment Programs** (8/25/2022)

**Navigating Early Career Funding Opportunities** (9/15/2022)

**Research Misconduct & Detrimental Research Practices** (10/14/2022)

**International Collaborations: Policies, Processes, & Partnerships** (11/9/2022)

**Human Subjects Research: Policies, Clinical Trials, & Inclusion** (12/6/2022-12/7/2022)

**Making the Most of the 2023 NIH Grants Conference** (1/12/2023)

**NIH Grants Conference: 2-Day Agenda** (2/1/2023-2/2/2023)

**Exhibit Hall: NIH Institute & Program Resources** (2/1/2023-2/2/2023)

**1:1 Meet the Experts** (2/1/2023-2/2/2023)

**Conference Networking Opportunities** (2/1/2023-2/2/2023)
Grants.Gov is Migrating to the Cloud…and will be down…


ANY NIH or AHRQ application due for the 9/25/2022 deadline is being shifted to a 10/3/2022 deadline.

REMEMBER! The new R01 Deadline is STILL 10/5/2022, so plan accordingly + give HS SPPO time to review.
Reminder: Change is Coming to Data Sharing in Applications/Awards

Understanding the New NIH Data Management and Sharing (DMS) Policy
(Recorded 8/11/2022; 1:27:37)

In this webinar, you will learn about DMS policy expectations, the applicability of the policy, how to prepare a Data Management and Sharing Plan, and considerations for sharing data responsibly. (Resources Slide Deck here)

Diving Deeper Into the New NIH Data Management and Sharing Policy
(Register here to watch live on 9/22/2022; 10:30-12:00 PM PDT)

In this webinar, you will provide more in-depth information on topics covered in the first webinar and expand upon topics including but not limited to privacy protections for human participant data and justifiable limits on data sharing.
Data Management & Sharing Guidance & Upcoming Requirements

NIH has created a website just for their upcoming policy on resource data. An overview of the policy can be found [here](#).

- For applications due on or after January 25, 2023, NIH will require researchers to prospectively plan for how scientific data will be preserved and shared through submission of a Data Management and Sharing Plan.

Investigators will be required to:

- Submit a [Data Management and Sharing plan](#) outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations.
- Comply with the Data Management and Sharing plan approved by the funding IC.
  - [NIMH Data Sharing for Applicants and Awardees](#) & [NIAID Data Management and Sharing Guidelines](#)
Data Management & Sharing Guidance & Upcoming Requirements

• The policy applies to all NIH-supported research that results in the generation of scientific data, regardless of funding mechanism. See [Research Covered Under the Data Management & Sharing Policy](#) for more details.

• The DMS Policy does not apply to research and other activities that do not generate scientific data, for example: training, infrastructure development, and non-research activities.

• During a research project’s funding period, compliance with the DMS plan will be determined by the NIH IC. After the end of the funding period, non-compliance with the DMS plan may be taken into account by NIH for future funding decisions for the recipient institution.

• FAQs page is [here](#) & information on Planning & Budgeting for DMS can be found [here](#).
Related NIH Notices

- **NOT-OD-21-013**: Final NIH Policy for Data Management and Sharing
- **NOT-OD-21-014**: Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan
- **NOT-OD-21-015**: Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing
- **NOT-OD-21-016**: Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research
- **NOT-OD-22-189**: Implementation Details for the NIH Data Management and Sharing Policy
- **NOT-OD-22-198**: Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023
Reminder: Forms-H Grant Applications are Coming January 25, 2023

**NOT-OD-22-195:** New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023

The following application forms include substantive form changes (i.e., new/deleted/modified fields). All other forms include only an OMB expiration date change.

- PHS 398 Research Plan Form
- PHS 398 Career Development Award Supplemental Form
- PHS 398 Research Training Program Plan*
- PHS Fellowship Supplemental Form*

**Key Changes:** A new "Other Plan(s)" attachment field has been added to the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form. Applicants must attach the required Data Management and Sharing Plan in this new field in FORMS-H applications.

* The 2023 NIH Data Management and Sharing Policy is not applicable to fellowship and institutional training grant applications, the new attachment field was added for potential future use with other plans.
More on Forms-H Grant Application Forms, Guidelines, & FOAs

- See High-level Summary of Form Changes in FORMS-H Application Packages for a full list of form changes.

- Application guides for FORMS-H application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2022.

- All active Parent and IC-issued FOAs with due dates on or after January 25, 2023 will be updated to add FORMS-H application packages between October 25, 2022 and November 25, 2022 with all application forms packages posted 30 calendar days or more prior to receipt dates.

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<td>• Applications submitted for due dates on or before January 24, 2023</td>
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<tr>
<td>• Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before January 24, 2023</td>
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<td>• Applications submitted by February 1, 2023 under NIH Continuous Submission Policy for the January 7, 2023 AIDS intended due date</td>
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<tr>
<td>• Applications submitted for due dates on or after January 25, 2023</td>
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<tr>
<td>• All application types (New, Resubmission, Renewal, Revision)</td>
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<tr>
<td>• Applications submitted early for intended due dates on or after January 25, 2023</td>
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Clarifying Digital e-Signatures for Other Support & How to Flatten a Secure PDF

There are two electronic signature (e-signature) options you can use at UC San Diego: DocuSign and Adobe Acrobat. Both of these options can create NIH's required audit trail. The onus falls on the department or school to maintain these records. The Central SPO will submit to NIH flattened versions of these Other Support PDFs that will not contain the certifications or properties.
• Log in through SSO
• Once logged in, DocuSign allows you to drag and drop the document you need to have signed.
• You can be both the host and signer.
• You can also be the host and forward an email to the person that needs to sign.
• For each step in the process, you will receive an email telling you it has to be signed as well as that it is complete.
• Once you download the document to your desktop, it will show that it has been signed and all the signatures are valid in Adobe Acrobat.
• When you download the document you will also download the Certificate of Completion which you must save for audit purposes.
  • Please do not upload this to eRA Commons or ASSIST to be sent to NIH.
Here is an example of the e-Signature and the Certificate of Completion.

Go [here](#) to sign into DocuSign at UC San Diego!
Adobe Acrobat has the "Fill & Sign" tool to add signatures, but this option only allows you to sign and not to both sign and certify the document. Thus, no audit trail is created where you can verify who actually signed the document and when.

When using Adobe Acrobat, make sure to select the "Certificates" tool.

You will have two options you can select:
- Digitally Sign option; or
- Certify (Visible Signature) option.

Both of the above options will work, but the latter of these two is the preferred choice.
Adobe Acrobat: Certificates Tool

Here is an example of the e-Signature (using the Certify (Visible Signature) option) and the Signature Properties showing who and when this was digitally signed.
How to Flatten a Secure PDF: 2 Options

Print to PDF vs. Drag & Drop Options

- In most cases, *Print to PDF* (instead of print to a specific printer) will work. However, some secure PDFs will not successfully *Print to PDF*. If this is the case, then you will have to *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 allow 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*. 
All NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov, as per the “NIH Policy on Dissemination of NIH-Funded Clinical Trial Information.”

- Currently, grant recipients receive a warning if they are not in compliance with clinical trial registration at 21 days after the enrollment of the first participant. They will also now see a new error if they are more than 30 days past this date.

- Similarly, the current warning for results reporting will change to an error; grant recipients will now receive an error when results are overdue by more than 12 months after the trial’s actual primary completion date.

UC San Diego Health

Health Sciences Sponsored Project Pre-Award Office (HS SPPO)

858.822.4109 (currently VM only)

vchsgrants@health.ucsd.edu

hssppo.ucsd.edu