HS SPPO Contacts Meeting

December 14, 2022
Agenda

UC San Diego Updates & Reminders
- Central SPOs Holiday Closure
- Final Progress Reports (RPPRs)

NIH Updates & Reminders
- New Application Forms & Updated Instructions are Coming (Again)!!!
- ClinicalTrials.gov Compliance
  - Diana Kim, Associate Director, RCI
- NIH Data Management and Sharing Plan (DMS)
  - David Minor, Director, Research Data Curation Program, UC San Diego Library
  - Ben Mooso, Director, Office of IRB Administration
UC San Diego Updates/Reminders
## Sponsored Project Offices Holiday Closure

Proposal Submission Deadlines

During the holiday season, the UC San Diego Campus (excluding the hospitals and clinics) will officially close from Friday, December 23, 2022, through Monday, January 2, 2023. The Sponsored Project Offices (OCGA, SIO-OCGA, and HS SPPO) will be closed during this period, and contract and grant officers and analysts will not be available to review and submit proposals or act on award negotiations/executions. We will reopen on Tuesday, January 3, 2023.

<table>
<thead>
<tr>
<th>Date &amp; Time</th>
<th>What</th>
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<tr>
<td>Before 8:00 AM on Thursday, December 15, 2022</td>
<td>The proposal package with draft science must be submitted to the appropriate SPO through Kuali PD.</td>
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<tr>
<td>Before 8:00 AM on Thursday, December 22, 2022</td>
<td>Both the finalized science section and the remainder of the final proposal package must be submitted to the appropriate SPO.</td>
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<td>After 12:00 PM on Thursday, December 22, 2022</td>
<td>No proposal is guaranteed submission if it is routed to the appropriate SPO, regardless of sponsor or actual deadline time.</td>
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<td>Before 4:30 PM on Thursday, December 15, 2022</td>
<td>NIH Non-Snap Progress Reports (RPPRs) due 1/1/23: if you’re working on a progress report with a budget component, please prepare the RPPR for review and route to your HS SPPO Analyst by December 15 for submission prior to December 22.</td>
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Reminder about Final Progress Reports

- Your PI’s Final Progress Reports (RPPR) are submitted with the assistance of OCGA. HS SPPO is not involved in post-award actions.
NIH Updates & Reminders
New Application Forms & Updated Instructions are Coming (Again)!!!

- Forms H are coming and will be replacing Forms G for all applications submitted to NIH for deadlines on or after January 25, 2023.

- Per NOT-OD-23-012, NIH is in the process of updating all active FOAs with due dates on or after January 25, 2023, to include information regarding Data Management and Sharing (DMS) Plan requirements in Sections IV, V, and VI. These updates are expected to be completed by December 25, 2022.

- For more information on these changes:
  - SF424 (R&R) – Forms H General Instructions
  - High-level Grant Application Form Change Summary: FORMS-H
  - FORMS-H: Instructions, Forms, and a Handy Checklist
  - Annotated Forms Sets for Forms H:
    - Single Project Applications
    - Multiple Project Applications
ClinicalTrials.gov Compliance

Diana Kim, Associate Director of RCI
1. Registration

2. Updating the record

3. Results posting

UCSD Principal Investigators are responsible for determining whether or not they are obligated to register a clinical trial and for any subsequent required updates, including results reporting.
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<tr>
<th>Entity</th>
<th>Registration</th>
<th>Results</th>
<th>Penalties</th>
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<tr>
<td>Food and Drug Administration (FDA)</td>
<td>Within 21 days of enrollment</td>
<td>Within 365 of Primary Completion Date</td>
<td>$13,000+/day/study, FDA sanctions, Loss of HHS funding and possible and Criminal proceedings</td>
</tr>
<tr>
<td>National Institutes of Health (NIH)</td>
<td>Within 21 days of enrollment</td>
<td>Within 365 of Primary Completion Date</td>
<td>Loss of grant funding (to include the institution) and other enforcement actions</td>
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<tr>
<td>International Committee of Medical Journal Editors (ICMJE)</td>
<td>Prior to enrollment of the first participant</td>
<td>Not Specified</td>
<td>Restricted from publishing in journals</td>
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<tr>
<td>National Cancer Institute (NCI)</td>
<td>Not Specified</td>
<td>Within 365 of Primary Completion Date</td>
<td>Loss of grant funding</td>
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• If the clinical trial is NIH-funded, expectations for clinical trial registration and summary results submission will be included in the terms and conditions of the award.

• Failure to comply may provide a basis for enforcement actions such as suspension of award activities, termination of awards, and/or withholding of funds (consistent with 45 CFR 75.371 and other authorities, as appropriate).
NOTICE OF NON-COMPLIANCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

October 19, 2022

XXX, Authorized Official

Reference [Grant #]

Dear XXX,

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

Grant Number: XXX
PI Name: XXX
Period of Performance: XXX-XXX
NIH Institute/Center: NIDA

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

NCTXXXXXXXX
[Study Title]
Primary Completion Date: XX/XX/XX

Compliance with the NIH policy is a term and condition of this grant award; however, NIDA has been unable to verify that results information has been submitted to ClinicalTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.
Research Compliance and Integrity
Phone: (858) 822-4939
Email: ctgov@ucsd.edu
Website: rci.ucsd.edu
NIH Data Management and Sharing Policy Update

David Minor
Director, Research Data Curation Program
UC San Diego Library
December 2022
- Previous NIH Policies
- The new NIH DMS Policy
- Planning for data sharing
- Resources at UC San Diego
Previous NIH Data Policies
2003 - NIH Data Sharing Policy

- Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible.
- Should be released no later than the date of publication acceptance.
- Data sharing and archiving costs are considered research costs.

Minimal work. Data sharing plans could be 2-3 sentences.
2008 - NIH Public Access Policy

● Ensures that the public has access to the published results of NIH-funded research.

● Requires NIH-funded scientists to submit final peer-reviewed journal manuscripts to the digital archive PubMed Central (PMC) upon acceptance for publication and no later than 12 months after publication.

Focused on publications
2014 - NIH Genomic Data Sharing Policy

- Applies to all NIH-funded research that generates large scale human or non-human genomic data
- Researchers need to write a basic genomic data sharing plan in the resource sharing plan section of their funding application
- Data (and relevant documentation) are to be shared in public repositories in a “timely manner” - generally at the time of acceptance of publication
- NIH institute will review compliance with the plan at annual progress reports
- Researchers need to plan for informed consent for human data

More rigorous data sharing but only for genomic data
The New NIH Data Policy
The new NIH policy in brief:

- Effective January 25, 2023
- Requires researchers seeking NIH funding for research to prospectively submit a 2-page plan outlining how scientific data from their research will be managed and shared
- List of NIH Activity Codes subject to the policy
- Researchers should “maximize the appropriate sharing of scientific data”
- Data should be shared as soon as possible, and no later than the time of an associated publication or end of performance period (whichever comes first)
- This plan represents the minimum requirements. NIH ICOs may expect more specificity in their plans - check funding opportunity announcements
What are the main new requirements?

1. A TWO PAGE Data Management and Sharing Plan that is **much more detailed** than previous sharing requirements.

2. The baseline expectation has shifted towards **data sharing as the default**.
What is included in the new NIH plan?
First, what is a Data Management Plan (DMP)?

- A document that addresses how you will manage and secure your data throughout the lifecycle of a research project.
- Can be both a required document for grants and a living document for research planning purposes.
What makes a good DMP?

- A good DMP should have a clear, organized and effective system to manage data throughout the project.
- Include plans for the data after the research is complete.
- The most important component of most federal data management plans is on data sharing and data preservation.
## Elements of the new NIH DMS Plan

In the (max) two-page document researchers will be asked to describe:

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<th>Data types</th>
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<td>Related tools, software, and/or code</td>
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<tr>
<td>Standards</td>
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<tr>
<td>Data preservation, access, and associated timelines</td>
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<tr>
<td>Access, distribution, or reuse considerations</td>
</tr>
<tr>
<td>Oversight of data management and sharing</td>
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Not all research data has to be shared

Justifiable reasons not to share data according to NIH:

- Informed consent will not permit or will limit the scope or extent of sharing
- Existing consent prohibits sharing or limits the scope or extent of sharing
- Privacy or safety of research participants would be compromised or place them at greater risk of re-identification or suffering harm
- Explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure
- There are restrictions imposed by existing or anticipated agreements (e.g., by third party funders, by partners, by other repositories, HIPAA)
- Datasets cannot practically be digitized with reasonable efforts
How are these plans evaluated/enforced?

- NIH program staff will assess the plans, grant reviewers can comment on the proposed budget for data management and sharing.

- Plans will be part of the **Terms and Conditions** for extramural awards and non-compliance can result in termination of award and impact future funding decisions.

- Compliance will be monitored by the relevant NIH institute during progress reports.
How do I pay for this?

Allowable costs may be included in NIH budget requests, including costs associated with:

- Curating data and developing supporting documentation (including data de-identification)
- Local data management considerations (infrastructure needed for local preservation)
- Preserving and sharing data through established repositories (data deposit fees)
Where should I share my data?

- Ideally, in a discipline or data-specific repository.
- NIH does not recommend specific repositories, but has a list of Open Domain-Specific Data Sharing Repositories and other NIH supported repositories.
- If no appropriate discipline or data-type specific repository is available:
  - UCSD Research Data Curation Program can help you identify an appropriate repository
  - The UCSD Library maintains a data repository
  - UC System manages Dryad
UCSD Library Research Data Curation Services

Whether you need assistance with creating a data management plan, training on data management best practices, guidance on depositing your data in a repository, help creating a digital object identifier (DOI) for your research outputs, or instruction on research computing skills, the Library’s Research Data Curation program is here to help.

The Library’s Research Data Curation Program offers free consultations to help with:

- Finding data standards
- Selecting data repositories
- Planning for data sharing

UC San Diego Library Research Data Curation NIH DMS Policy Webpage
NIH Data Sharing Policy Update

NIH has issued a new Final NIH Policy for Data Management and Sharing, which will require NIH funded researchers to prospectively submit a Data Management and Sharing Plan (DMSP) outlining how scientific data from their research will be managed and shared. On January 25, 2023, the new policy will come into effect and replace the 2003 NIH Data Sharing Policy currently in effect.

If you plan to generate scientific data and apply for an NIH grant, you must submit a DMSP as part of the Budget Justification section of your grant application.

What do I include in a NIH Data Management and Sharing Plan?

In these max two-page documents, you will describe your:

- Data type – an overview of the data you are collecting
- Related tools, software, and/or code – what is needed to understand and/or use that data
- Standards – if there are any standardized file formats, data dictionaries, etc
- Data preservation, access, and associated timelines – when and where you will publicly share your data
- Access, distribution, or reuse considerations – any special considerations for securing the data or protecting patient privacy
- Oversight of data management and sharing – who will carry out this plan

Where can I find guidance or additional information?

To help the UC San Diego research community prepare for implementation of the new policy, the following resources are available:

- 2023 NIH Policy Data Management Guidance Documentation
  - DMSP Checklist for Researchers
  - Glossary of terms
- NIH Writing A Data Management and Sharing Plan

Official NIH supplemental documentation for the 2023 DMSP policy:

- Elements of an NIH Data Management and Sharing Plan
- Allowable Costs for Data Management and Sharing
- Selecting a Repository for Data Resulting from NIH-Supported Research
- Which Policies Apply to My Research?
- NIH Data Sharing for Applicants and Awardees

Visit the page on public access and open science to learn more.

How do I get started writing a DMSP?

The Data Management Plan Tool, or DMPTool, is a free resource for anyone to use that helps researchers create data management sharing plans as they write their funding proposal.

NIH Sample Data Management and Sharing Plans:

- Clinical and/or MRI data from human research participants
- Genomic data from human research participants
- Genomic data from a non-human source
- Secondary Data Analysis

Additional DMSP Samples:

- Sample Data Management Plans
Contact Us

UC San Diego Library Research Data Curation Program

Research-Data-Curation@ucsd.edu

Slides Acknowledgement: Ariel Deardorff, UCSF; Reid Otsuji, UCSD
Questions?
IRB EXPECTATIONS FOR DATA MANAGEMENT AND SHARING

Ben Mooso
Director
Office of IRB Administration
Why Worry at the Proposal Stage?

• Make sure the proposed data sharing plan is allowable
  • Don’t want to have to request changes after the fact

• Avoid proposal and IRB mis-match
  • I.e. avoid headaches later

• Most things are possible with consent
  • Makes sure you know what needs to be in the consent before you even start
NIH Requirements

What is NIH Requiring?
• A detailed plan for how data will be appropriately shared
• A default toward sharing data
• Sharing data as soon as possible

What isn’t NIH Requiring?
• Sharing of identifiable data
IRB Considerations for Data Sharing

• Is the type of sharing necessary?
  • E.g. aggregate data, individual de-identified data, identifiable data, etc.

• Have the risks of sharing been minimized?
  • E.g. identifiable data isn’t shared when it doesn’t need to be

• Is there a consent process for the study?

• Is the sharing discussed in the consent document?

• Is the type of sharing allowed by the consent used in the study?
IRB “Green Lights”

All are true:
• Data will only be shared in a de-identified manner
• Study has a consent process
• Data sharing is “baked-in” to the consent
  • No opt-out
• Consent uses standard de-identified sharing language from our template:
  The [choose as appropriate: data and/or specimens] we collect with your identifiable information (for example, your name, medical record number, or date of birth) as a part of this study may be used to answer other research questions or may be shared with other investigators for other research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask for your consent for the use or sharing of your [choose as appropriate: data and/or specimens] in other research. [Include if applicable:] In addition, data that have been de-identified will be uploaded to [name of repository] for other researchers to access and use.
IRB “Yellow Lights”

Talk to the IRB if any of the following are true:

• Data will be shared in an identifiable manner

• Study does not have a consent process

• Data sharing will be optional in the consent
Contact Us

To contact the IRB with data sharing questions, please email us at irb@ucsd.edu.

We will be happy to walk through the particulars of the study and the proposed data sharing plan.
QUESTIONS?