Quarterly Research Administration Meeting

September 28, 2022
Agenda

• Welcome
• NIH Data Sharing Policy 2023
• Area Updates:
  – Sponsored Projects Administration
  – Contracts & Grants Accounting
  – IACUC Guidance Pages
  – Human Research Protections
  – Electronic Research Administration
• Q&A and Closing
Breakouts

• Groups of 4+
• 6 minutes
• Introductions:
  – Name
  – Department
  – Your favorite job-related responsibility and why
  – Or, discuss favorite Zoom backgrounds
Agenda

• Welcome

• **NIH Data Sharing Policy 2023**

• Area Updates:
  – Sponsored Projects Administration
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  – Human Research Protections
  – Electronic Research Administration

• Q&A and Closing
Overview of the 2023 NIH Data Management and Sharing Policy

Mitchell Brown, Scholarly Communications Librarian
mcbrown@uci.edu
Wasila Dahdul, Data Curation Librarian
wdahdul@uci.edu

QRAM, September 28, 2022

This presentation uses content from the NIH Scientific Data Sharing website
The benefits and mission of ORCID (Open Researcher & Contributor Identifier) are best achieved when organizations and individuals are participating in the ORCID ecosystem.

https://orcid.org
2023 NIH Data Management and Sharing (DMS) Policy

NIH has a longstanding commitment to making the results of NIH-funded research available.

Responsible data management and sharing has many benefits, including accelerating the pace of biomedical research, enabling validation of research results, and providing accessibility to high-value datasets.

DMS Policy will create a consistent minimum expectation for all research supported by the agency.
DMS Policy Key Points

- Requires researchers to prospectively plan for how scientific data will be managed and ultimately shared.
- Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of "scientific data".
- Submission of a 2 page DMS Plan with grant proposals.
- Compliance with the Plan approved by the funding NIH Institute, Center, or Office; updates to Plan in annual progress reports.

Effective January 25, 2023
Limitations on Sharing

DMS Plans should maximize appropriate sharing

However, justifiable ethical, legal, and technical factors for limiting sharing include:

- Informed consent will not permit or limits scope of sharing or use
- Privacy or safety of research participants would be compromised and available protections insufficient
- Explicit federal, state, local, or Tribal law, regulation or policy prohibits disclosure
- Restrictions imposed by existing or anticipated agreements with other parties
Elements of the DMS Plan

- **Data type**
  - Identify data to be preserved and shared
- **Related tools, software, code**
  - Tools and software needed to access and manipulate data
- **Standards**
  - Standards to be applied to scientific data and metadata
- **Data preservation, access, timelines**
  - Repository to be used, persistent unique identifiers, data availability timeline
- **Access, distribution, reuse considerations**
  - Description of factors for data access, distribution, or reuse
- **Oversight**
  - Plan compliance will be managed/monitored and by whom

See [Writing a Data Management & Sharing Plan](#) for details
Format of the DMS Plan

- Plans should be no more than 2 pages in length
- Optional format template will be available in Fall 2022

Timeline for Sharing Data

**When?** As soon as possible:

- No later than the time of a *publication of findings* in a peer-reviewed journal OR at the *end of the award*, whichever comes first

**For how long?**

- Varies across disciplines; consider relevant requirements and expectations
  - Data repository policies
  - Journal policies
Repositories for Sharing and Preserving Data

- NIH encourages the use of established repositories
  - Doing so improves the FAIRness of data - Findable, Accessible, Interoperable, Reusable
- NIH ICs may designate specific data repositories
  - See Selecting a Data Repository for details

UCI Libraries can help researchers select the appropriate data repository for their research
- General-purpose data repository that makes data discoverable, freely reusable, and citable
- Free for UCI researchers
- Log in with UCI email and link to ORCID ID

https://datadryad.org/stash
Costs associated with data management and sharing

Allowable costs (must be incurred during the performance period)

- Curating data and developing supporting documentation
- Preserving and sharing through repositories
- Local data management considerations

Unallowable costs

- Infrastructure costs typically included in indirect costs
- Costs associated with the routine conduct of research (e.g., gaining access to research data)

See Budgeting for Data Management & Sharing for details
UCI Resources
- Create data management plans that meet funder requirements
- Templates for 22 federal and private funders
- Free for UCI researchers
- Log in with UCI email and link to ORCID ID

https://dmptool.org
- Draft “generic” 2023 NIH template in development
- Specific NIH Institute and Center templates forthcoming
UCI Library Guide on Research Data Management

Research Data Management: New 2023 NIH Data Sharing Policy

Overview of 2023 NIH Data Management and Sharing Policy

The National Institutes of Health (NIH) has issued a Final NIH Policy for Data Management and Sharing (effective January 25, 2023), requiring NIH funded researchers to submit a plan outlining how scientific data from their research will be managed and shared. The new policy will replace the currently in effect 2003 NIH Data Sharing Policy. The new policy requires submission of a 2-page (max) Data Management and Sharing Plan (DMSP) describing the following:

1. Data type
2. Related tools, software, and/or code
3. Standards
4. Preservation, access, and associated timelines
5. Access, distribution, and reuse considerations
6. Oversight of data management and sharing

FAQs for NIH 2023 Data Management and Sharing Policy

General Data Sharing

- Why should I publicly share my data? (a)

https://guides.lib.uci.edu/datamanagement/NIH_2023_data_sharing_policy
Questions?

Mitchell Brown, mcbrown@uci.edu

Wasila Dahdul, wdahdul@uci.edu

Digital Scholarship Services, libdss@uci.edu
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• Q&A and Closing
SPA staff introductions and updates
Enhanced NIH Other Support

Adriana Ascencio
Contract and Grant Officer, SPA

Maria Diaz
Contract and Grant Supervisor, SPA
NIH Biosketch & Other Support

The National Institutes of Health (NIH) has issued new requirements for Other Support reporting and Biographical Sketches (Biosketches) submitted on or after January 25, 2022.

The information provided below summarizes these new requirements.

https://research.uci.edu/sponsored-projects/proposal-submission/nih-biosketch-and-other-support/
Questions?

Adriana Ascencio
ascencio@uci.edu

Maria Diaz
mgdiaz1@uci.edu
Federal Updates

Nancy Lewis
Executive Director, Sponsored Projects Administration
NSF Update

- Federal PRA clearance process
  - April 13, 2022 (posted in Federal Register)
  - June 13, 2022 (comments were due)
  - September 7, 2022 (with OMB for final review)

- PAPPG issued and posted on NSF website
  - October 2022

- PAPPG becomes effective
  - January 2023
PAPPG (NSF 23-1) Proposed Revisions

- Transition from FastLane to Research.gov
- Use of Broad Agency Announcements (BAAs) and the BAA Management System (BAAM)
- Use of Concept Outlines and new ProSPCT tool
PAPPG (NSF 23-1) Proposed Revisions

• Plan for Safe & Inclusive Field, Vessel and Aircraft Research PSI-FVAR or PSI
  • Fieldwork can present unique challenges such as extreme conditions, social isolation, limited communication, and can take place in locations with different social norms
  • New guidance is proposed to be added to the Special Information and Supplementary Documentation section of the PAPPG
  • Research in the field is defined as data/information/samples being collected off-campus or off-site.
  • The proposed guidance shares NSF’s expectations, as well as the content of the new supplementary document.
  • The two-page PSI-FVAR will be reviewed as an integral part of the proposal, and will be considered under intellectual merit, broader impacts, or both, as appropriate for the project being proposed.
PAPPG (NSF 23-1) Proposed Revisions

- Biographical Sketch and Current and Pending Support - SciENcv Implementation
  - Fillable formats and SciENcv will continue to be available
  - Certification language will be incorporated into both formats
  - October 2023 – submission via SciENcv becomes required
PAPPG (NSF 23-1) Proposed Revisions

• Revision of GOALI requirements
• Incorporation of new section on Scientific Integrity
• Addition of New Check Boxes for the Proposal Cover Sheet
  • Potential Life Sciences Dual Use Research of Concern
  • Plan for Safe and Inclusive Field/Vessel/Aircraft Research
Goodbye FastLane Proposal Preparation…Hello Research.gov

• Effective with the implementation of the PAPPG in January 2023, FastLane will be removed as a submission option from all solicitations.
• NSF has gradually been removing FastLane as a submission option.
• Grants.gov remains an option for most proposals.

IMPORTANT INFORMATION AND REVISION NOTE ABOUT RESEARCH.GOV PROPOSAL PREPARATION:

Innovating and migrating proposal preparation and submission capabilities from FastLane to Research.gov is part of the ongoing NSF information technology modernization efforts, as described in Important Notice No. 147. In support of these efforts, proposals submitted in response to this program solicitation must be prepared and submitted via Research.gov or via Grants.gov and may not be prepared or submitted via FastLane.
## FastLane Proposal Preparation and Submission Decommissioning Deadlines

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<th>Action</th>
<th>Deadline</th>
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<tbody>
<tr>
<td><strong>SUBMIT NEW</strong></td>
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<tr>
<td>Last day to submit new proposals in FastLane</td>
<td>Friday, January 27, 2023 (5:00 PM submitter’s local time)</td>
</tr>
<tr>
<td><strong>EDIT EXISTING</strong></td>
<td></td>
</tr>
<tr>
<td>Last day to submit proposal file updates/ budget revisions in FastLane</td>
<td>Friday, September 29, 2023 (5:00 PM submitter’s local time)</td>
</tr>
<tr>
<td><strong>VIEW EXISTING</strong></td>
<td></td>
</tr>
<tr>
<td>Last day to download FastLane submitted proposals and print FastLane in-progress proposal PDFs</td>
<td>Friday, September 29, 2023 (11:00 PM Eastern Time)</td>
</tr>
</tbody>
</table>
Upcoming Research.gov Enhancement: Supplemental Funding

- As of October 24th, Research.gov will support preparation and submission of supplemental funding requests, including Career-Life Balance requests per PAPPG Chapter II.E.8.
- Requests can be submitted in Research.gov if the award was the result of a proposal submitted in FastLane or Grants.gov
- New supplemental funding requests can be submitted in FastLane until January 27, 2023
- Research.gov Supplemental Funding Request Demo Site will also be available on October 24th
NSF Outreach Opportunities

• Fall 2022 NSF Grants Conference – November 14-17
  • Registration opens on October 13th
  • Proposal Preparation and Merit Review
  • Award Management
  • Directorate-specific sessions

• NSF Policy Office Webinar Series
  • Topic-specific sessions
  • Next session on September 27th will cover the use of Concept Outlines
  • Registration now open

• Resource Center
  • On-demand presentations – searchable by topic and year

Visit: https://nsfpolicyoutreach.com/
Resources

• Policy Office Website
• Current PAPPG (NSF 22-1)
• For-Comment Draft PAPPG (NSF 23-1)
• NSF Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending Support
• Current and Pending Support FAQs
NIH Update
Publication of the Revised NIH GPS for Fiscal Year 2022

• Update is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2021, even though the updated GPS will be issued on or after December 31, 2022.
  • Previous versions of the NIH GPS remain applicable as standard terms and conditions of award for all NIH grants and cooperative agreements with budget periods that began prior to October 1, 2021.

• NIH will continue to publish interim grants policy changes and/or clarifications through the issuance of NIH Guide Notices, available here.

• As is standard, a significant changes table will be published alongside the GPS update.
Implementation of Changes to the Biographical Sketch and Other Support Format Page

• NIH requires applicants and recipients to use the updated Biosketch and Other Support format for applications, Just-in-Time (JIT) Reports, and Research Performance Progress Reports (RPPRs).
  • Effective January 25, 2022, electronic signatures and supporting documentation are required
  • Failure to follow the appropriate formats may cause NIH to withdraw applications from or delay consideration of funding.

• Applicants and recipients remain responsible for disclosing all research endeavors regardless of the version of the forms used.

Learn more: NOT-OD-21-110
Learn More: Biosketch FAQs & Other Support FAQs
Reminder: Submission Validations for Clinical Trial Registration and Results Reporting

• Recipients will continue to receive an error preventing submission of an RPPR if there are studies involving clinical trials where:
  • Registration is due and no National Clinical Trial (NCT) number has been entered into the Human Subjects and Clinical Trials Information (HSCT) form or
  • Results are due and have not been submitted in ClinicalTrials.gov.

• To address the delinquent registration error, the recipient will be required to:
  • Provide the NCT number issued by ClinicalTrials.gov, or
  • Provide the ClinicalTrials.gov registration receipt that is received upon submission of the trial registration information to ClinicalTrials.gov.

• To address the results reporting error, the recipient will be required to:
  • Submit the trial results information to ClinicalTrials.gov or
  • Provide the ClinicalTrials.gov submission receipt for a (1) Good Cause Extension request or (2) Certification of Delayed Submission of Results Information from ClinicalTrials.gov.

• Recipients must take action to bring the clinical trial into compliance in order to clear validation errors, submit the RRPR, and continue to receive funding.

Learn more: NOT-OD-22-008
FORMS-H Grant Application Forms & Instructions Coming for Due Dates On or After January 25, 2023

• Effective for due dates on or after January 25, 2023, applicants must use FORMS-H application packages.

• Key forms change to add new “Other Plan(s)” single attachment to:
  • PHS 398 Research Plan
  • PHS 398 Career Development Award Supplemental Form
  • PHS 398 Research Training Program Plan
  • PHS Fellowship Supplemental Form

• Necessary for implementation of 2023 NIH Data Management & Sharing Policy (see NOT-OD-21-013; NOT-OD-22-189).

• See High-level summary of FORMS-H application form changes for more information.
  • Additional RPPR and other eRA system changes for DMS policy implementation (e.g., Grant folder and JIT module) are planned and will be communicated as details are finalized.

Learn more: NOT-OD-22-195
FORMS-H Timeline Highlights

- Fall 2022: Additional FORMS-H implementation details will be communicated via Guide notice.
- October 25, 2022: FORMS-H Application Guide will be posted to the How to Apply – Application Guide page.
- October 25, 2022: New funding opportunities with due dates on or after January 25, 2023 will begin to be published with FORMS-H application forms packages.
- October 25 – November 25, 2022: Active Parent and IC-issued funding opportunities with due dates on or after January 25, 2023 will be updated to add FORMS-H application forms packages.
- January 25, 2023: First FORMS-H application due date.

Learn more: NOT-OD-22-195
Questions?

Nancy Lewis

nrlewis@uci.edu
Breakouts

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- 6 minutes
- Introductions:
  - Name
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Contracts & Grants Accounting

Beata Najman
Director, Extramural Funds Accounting
Contracts & Grants Accounting Updates

- New C&G Accountants
- Award Closeouts, Cost Sharing, and PCS Reporting Deadlines
- NSF Awards with Canceling Funds

- C&G Training in October:
  - Introduction to Fund Management - Thursday, October 20, 10:30 am – 12:00 pm
  - Direct vs. F&A - Tuesday, October 25, 10:30 am – 12:00 pm
  - Ledger Reading and Award Closeout - Thursday, October 27, 10:15 am – 12:00 pm
Travel Expenses on Federal Awards

- Travel costs, including costs of transportation, lodging, meals, and incidentals, are an allowable cost on Federal awards. Employees should be on travel status and on official business related to the Federal award (UG §200.475).

- The employee’s travel should directly benefit the project goals. In most cases, this means an employee should be paid through the grant in order to charge travel to it. Documentation for travel costs charged to a Federal award must justify:
  
  1. Participation of the individual is necessary to the Federal award
  
  2. The costs are reasonable and consistent with the institutional travel policy
## Travel Monitoring and Compliance

| Ensure that all future travel is approved by the PI in writing or on an internal form before any travel arrangements are made |
| Make sure that the person asking for a reimbursement works on the project and can be reimbursed for this type of travel, or is specified in the budget and budget justification in some other way as authorized to travel for the benefit of the project (i.e., participant support travel) |
| Ensure that all reimbursable travel costs are allowable, reasonable, and the institutional travel policy is consistently applied |
| Ensure that the most economic mode of transportation is used, and have good understanding of when under your institutional policy exceptions to coach travel may be allowed |
| Determine allowed amounts for lodging, subsistence, and other travel related expenses, and type of allowed reimbursement (actual cost basis, per diem, or a combination of the two) |
| Well document business purpose (i.e., conference schedule and agenda) and dates of each trip, including specifying personal days and their full exclusion from the travel reimbursement |
| Advise travelers to not pay for each other during travel |
| If there is a possibility that a part of a trip cost was covered by another institution, ensure that this is clearly specified and documented in the reimbursement, and not reimbursed a second time |
| Obtain PI’s signature or other form of approval for all travel paid from the award and make sure that all required backup is clear and retained for audit purposes |
Foreign Travel

- Travelers are required by the **Fly America Act** use U.S. flag air carrier service, or foreign carriers that code share with a U.S. flag air carrier, for all transportation services funded by the U.S. government if service provided by such a carrier is available.

- **Code sharing** occurs when a ticket is issued by one airline but operated by another. This happens when a U.S. flag carrier leases seats on a foreign carrier. In order for the cost of airfare to be an allowable expense on a Federal award, tickets must identify the U.S. flag air carrier’s designator code and flight number.
Foreign Travel

- **Open Skies Agreements** – agreements between the U.S. government and the governments of foreign countries that allow travelers to use air carriers from these countries for government-funded international travel. The United States currently has Open Skies Agreements with the European Union¹, Australia, Switzerland and Japan².

- The rights given to airlines under the Open Skies Agreement don’t apply to travel funded by the Secretary of Defense or the Secretary of a military department. As a result of this additional restriction, **Department of Defense (DOD) requires that all foreign travel takes place on U.S. flag air carrier services** (with very few exceptions).

¹ UK is no longer a member of the EU and the Open Skies Agreement with EU no longer applies to UK.
² If a “City Pair” fare exists between the cities of origin and destination, Australian, Swiss, or Japanese air carrier cannot be used.

Questions?

Beata Najman

bnajman@uci.edu
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Updated IACUC Guidance

UCI-IACUC website:  [https://research.uci.edu/animal-care-and-use](https://research.uci.edu/animal-care-and-use)

- **Do You Need IACUC Review?** – *when in doubt, please ask us!*  [IACUC@uci.edu](mailto:IACUC@uci.edu)
  - Obtaining Animal Tissues or Products for UCI Research/Teaching Activities
- **Determination and Justification of Animal Numbers**
- **Sanitation/Disinfection of Researcher-Maintained Animal Equipment**
Questions?

Diana Li

dwli@uci.edu
Breakouts

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  – Department
  – Your favorite job-related responsibility and why
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Human Research Protections (HRP)

Jessica Sheldon
Assistant Director, Human Research Protections
HRP staff introductions and updates
Human Research Protections (HRP) has updated the Kuali Research Protocols (KRP) form for new projects to address feedback provided from UCI faculty, staff, students, IRB members, and IRB partners. Below is a list of notable updates:

<table>
<thead>
<tr>
<th><img src="image1.png" alt="Diagram" /></th>
<th>New Project Status section (at the bottom of the form) This section will be updated by HRP staff when the transaction status has changed.</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image2.png" alt="Diagram" /></td>
<td>New distinct form for Social/ Behavioral/ Educational research</td>
</tr>
</tbody>
</table>
| ![Diagram](image3.png) | - Simplified forms for Expanded Access, Right to Try, and Humanitarian Use Device  
- Revised workflow for Emergency Use |
| ![Diagram](image4.png) | - Reformatted with large font for prompts and normal font for guidance  
- Revised prompts for further clarification  
- Enabled text formatting in sections requiring more detailed information  
- Reorganized with more section breaks  
- Revised form logic for accuracy |
Questions?

Jessica Sheldon

jessica.sheldon@uci.edu
EQUIP Updates

- UCI HRP Webpage – Clinicaltrials.gov
- How To Register and Update Your Study On ClinicalTrials.gov
- Checklist To Address Common Errors In The PRS Record
- OHRP Guidance - Informed Consent Posting Requirement
Questions?

Anu Mathur
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Electronic Research Administration (ERA) Updates

Barbara Inderwiesche
Director, ERA
ERA Updates

• Removing COVID question in KR PD

• Be on lookout for KR Protocols Survey in October.
  – Intended for users who have created a NEW protocol
Effort

– Field in KR PD that carries through to award

– Would you use this field if it meant you could report on it? <Launch Poll>
We need your feedback!
### Proposals Created - All

<table>
<thead>
<tr>
<th>School Name</th>
<th>Proposals Created</th>
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<tr>
<td>SCHOOL OF MEDICINE</td>
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<tr>
<td>DFA ADMINISTRATION</td>
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### 3 Year Success Rate - All

- **Total Proposals Created**: 5,498
- **3 Year Success Rate**: 21.26%

### Fiscal Year - All

- **FY 2021 Total Cost**: $2,466,736,004.29
- **FY 2022 Total Cost**: $2,261,563,528.22

### Quarter - All

- **2021 Q1 Total Cost**: $1,048,867,716.74
- **2021 Q2 Total Cost**: $1,133,661,283.76
- **2021 Q3 Total Cost**: $1,228,347,472.00
Questions?

Barbara Inderwiesche
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OR
era@research.uci.edu
Join us next time!

January 2023, date TBD

Do you have a topic you want to hear about?
Do you have a topic that you want to share?
email era@research.uci.edu