

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



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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

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INFO

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> USE YOUR ORCID ID

Include your ORCID identifier on your Webpage, when you submit publications, apply for grants, and in any research workflow to ensure you get credit for your work.

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 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

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DMS Policy Key Points

- Requires researchers to <u>prospectively plan</u> 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 <u>DMS Plan</u> with grant proposals
- <u>Compliance</u> 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

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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

OMB No. 0925-0001 and 0925-0002 (Rev. 07/2022 Approved Through TBD)

PREVIEW – DRAFT

DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on sharing.nih.gov. The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no "form page" for the Data Management and Sharing Plan. The DMS Plan may be provided in the format shown below.

Element 1: Data Type

- A. Types and amount of scientific data expected to be generated in the project:

 Summarize the types and estimated amount of scientific data expected to be generated in the project.
- B. Scientific data that will be preserved and shared, and the rationale for doing so:

 Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

https://grants.nih.gov/sites/default/files/DMS-Plan-blank-format-page.pdf

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

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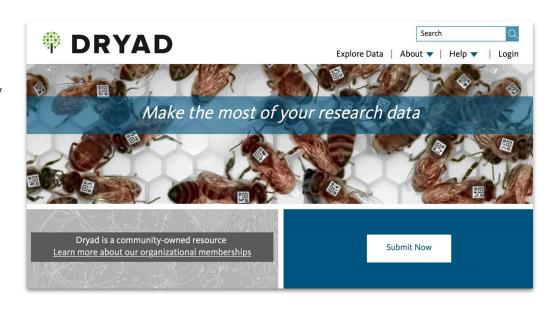
Repositories for Sharing and Preserving Data

- NIH encourages the use of established repositories
 - o 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 <u>Budgeting for Data Management & Sharing</u> for details

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UCI Resources



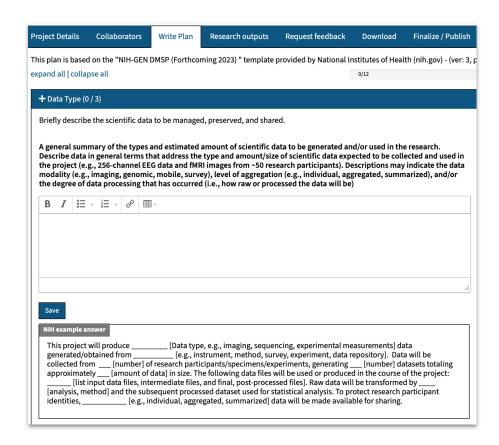
- Create data management plans that meet funder requirements
- Templates for 22 federal and private funders
- Free for UCI researchers
- Log in with UCI email and link to ORCID ID



https://dmptool.org

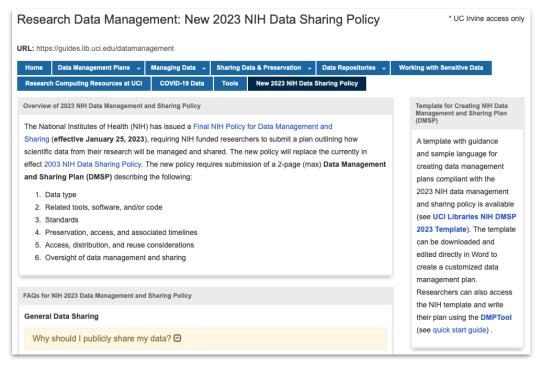


- Draft "generic" 2023 NIH template in development
- Specific NIH Institute and Center templates forthcoming



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UCI Library Guide on Research Data Management



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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SPA staff introductions and updates

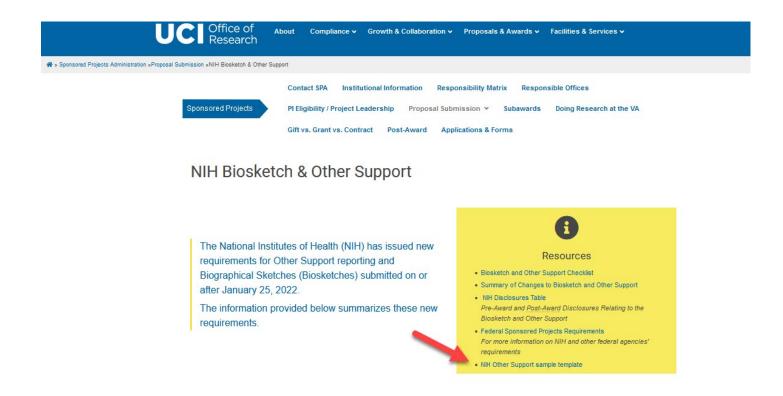


Enhanced NIH Other Support

Adriana Ascencio
Contract and Grant Officer, SPA

Maria Diaz
Contract and Grant Supervisor, SPA





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



Proposed Proposal & Award Policies & Procedures Guide (PAPPG) (NSF-23-1) Anticipated Timeline

- 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









- 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



- 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.



- 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



- 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.

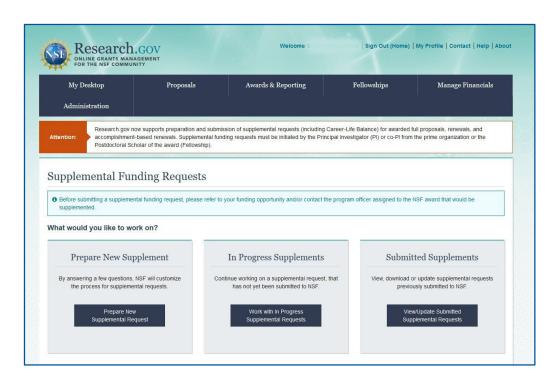


FastLane Proposal Preparation and Submission Decommissioning Deadlines

Action	Deadline
SUBMIT NEW	
Last day to submit new proposals in	Friday, January 27, 2023 (5:00 PM submitter's
FastLane	local time)
EDIT EXISTING	
Last day to submit proposal file updates/	Friday, September 29, 2023 (5:00 PM
budget revisions in FastLane	submitter's local time)
VIEW EXISTING	
Last day to download FastLane submitted	Friday, September 29, 2023 (11:00 PM Eastern
proposals and print FastLane in-progress	Time)
proposal PDFs	
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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 <u>Chapter II.E.8.</u>
- 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 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 FAOs & 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 <u>ClinicalTrials.gov</u> registration receipt that is received upon submission of the trial registration information to <u>ClinicalTrials.gov</u>.
- To address the results reporting error, the recipient will be required to:
 - Submit the trial results information to <u>ClinicalTrials.gov</u> 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 <u>2023 NIH Data Management & Sharing Policy</u> (see <u>NOT-OD-21-013</u>; <u>NOT-OD-22-189</u>).
- See <u>High-level summary of FORMS-H application form changes</u> 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 <u>How to Apply – Application Guide</u> 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 <u>Parent</u> 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



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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

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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.

https://www.gsa.gov/policy-regulations/policy/travel-management-policy/fly-america-act



Questions?

Beata Najman

bnajman@uci.edu



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IACUC Guidance Pages

Diana Li
Office of Research Administration



Updated IACUC Guidance

UCI-IACUC website: https://research.uci.edu/animal-care-and-use



- Do You Need IACUC Review? when in doubt, please ask us! IACUC@uci.edu
 - Obtaining Animal Tissues or Products for UCI Research/Teaching Activities
- Determination and Justification of Animal Numbers
- <u>Sanitation/Disinfection of Researcher-Maintained Animal Equipment</u>



Questions?

Diana Li

dwli@uci.edu



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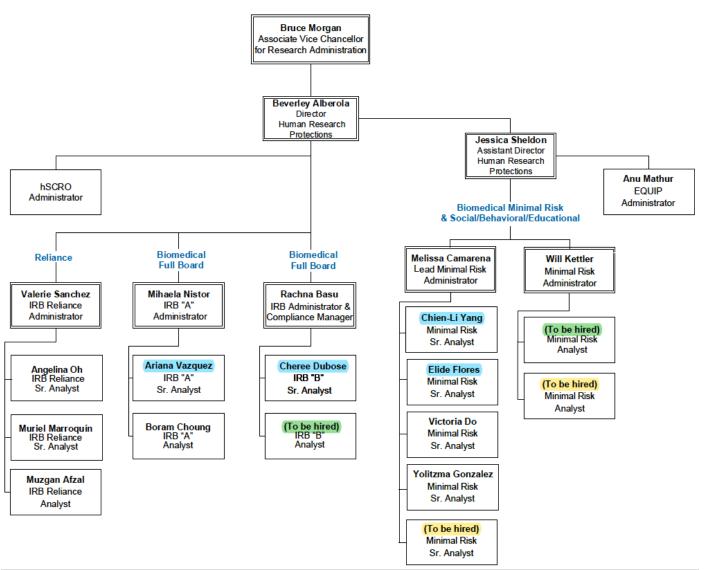
Human Research Protections (HRP)

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:

●→◆ ■←●	New Project Status section (at the bottom of the form) This section will be updated by HRP staff when the transaction status has changed.
1	New distinct form for Social/ Behavioral/ Educational research
	 Simplified forms for Expanded Access, Right to Try, and Humanitarian Use Device Revised workflow for Emergency Use
	 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



Human Research Protections EQUIP

Anu Mathur

IRB Education & Quality Improvement (EQUIP)

Administrator



EQUIP Updates

- UCI HRP Webpage Clincialtrials.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

anuradhm@uci.edu



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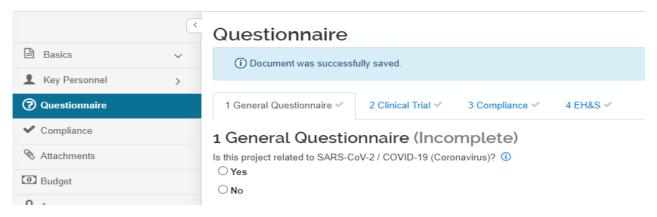
Electronic Research Administration (ERA) Updates

Barbara Inderwiesche Director, ERA



ERA Updates

Removing COVID question in KR PD

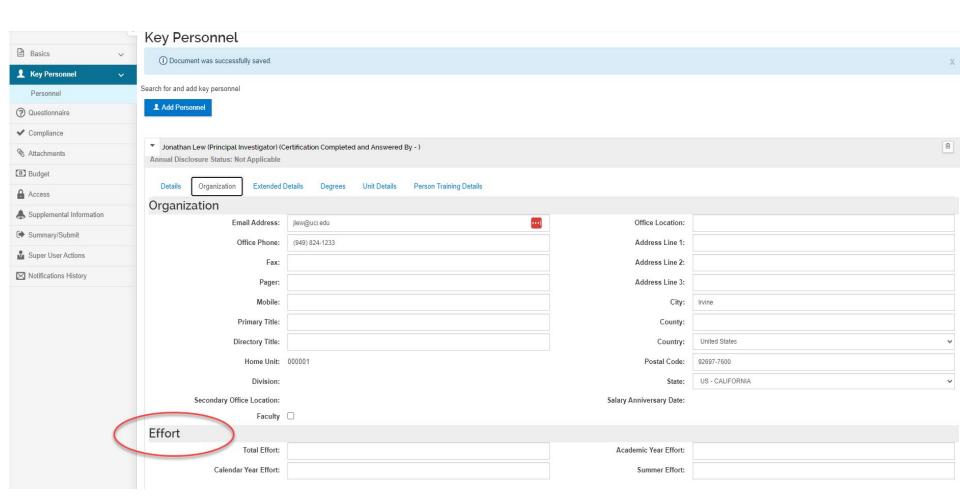


- Be on lookout for KR Protocols Survey in October.
 - Intended for users who have created a NEW protocol



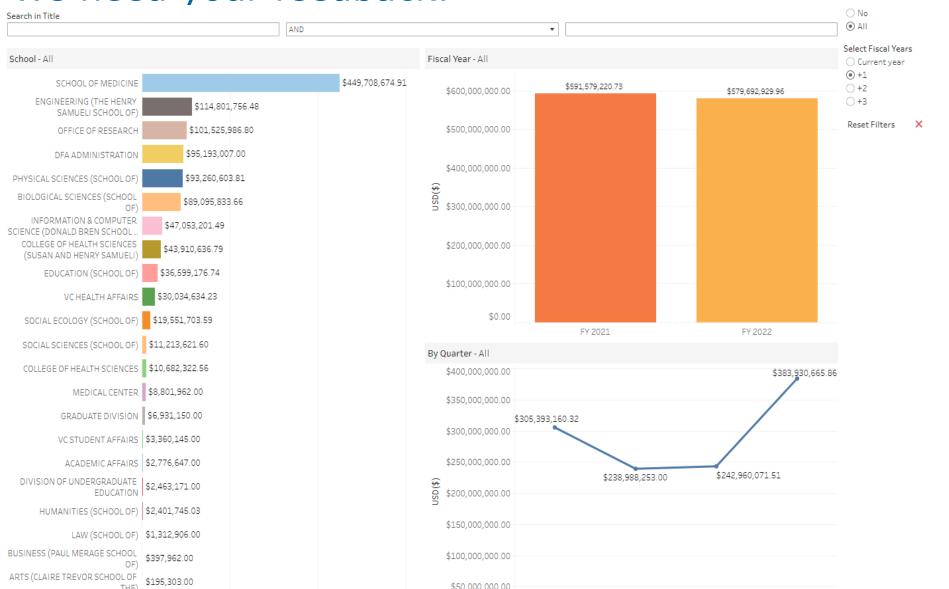
Effort

- Field in KR PD that carries through to award
 - Would you use this field if it meant you could report on it? <Launch Poll>

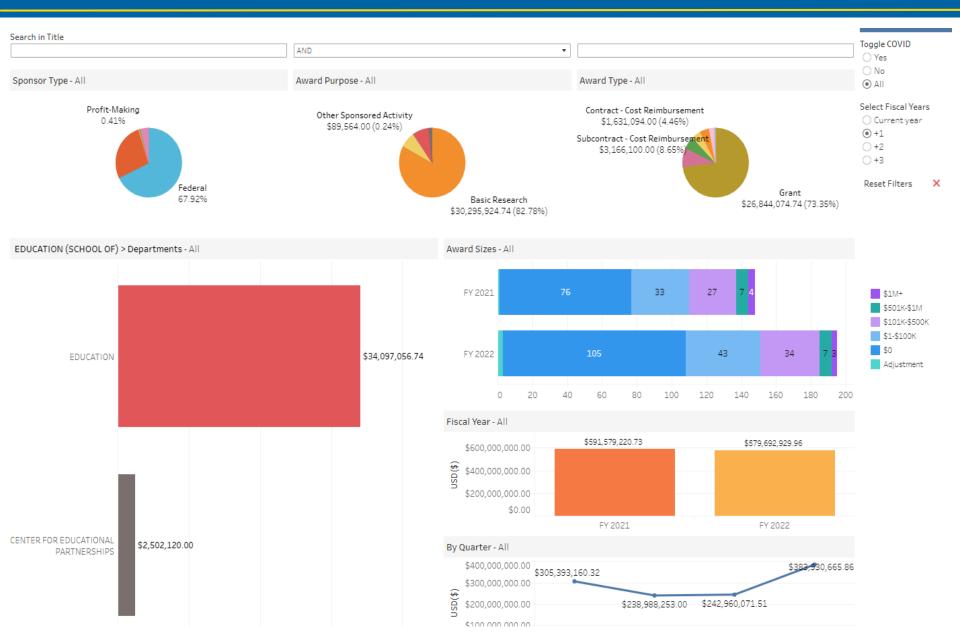




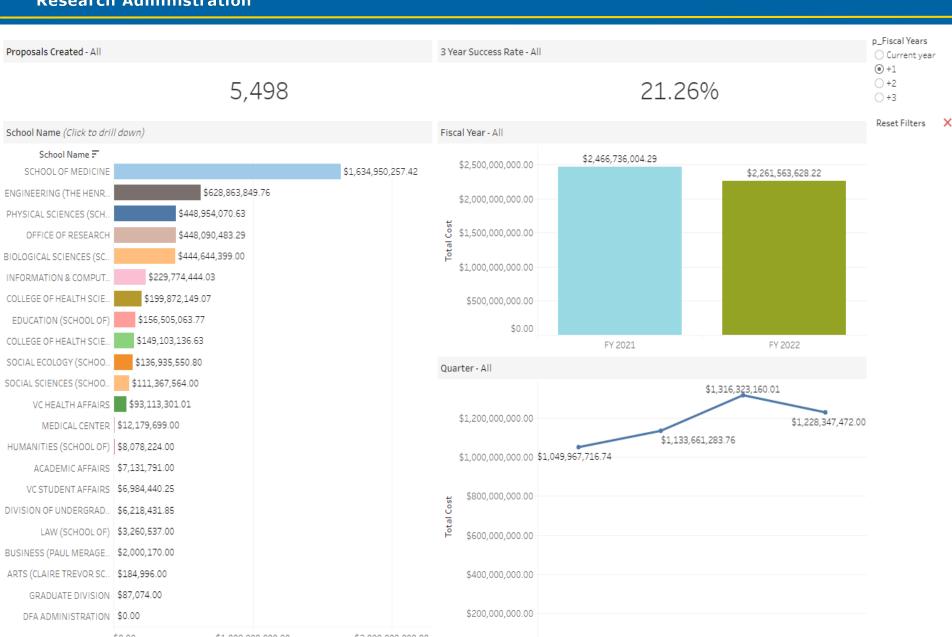
We need your feedback!



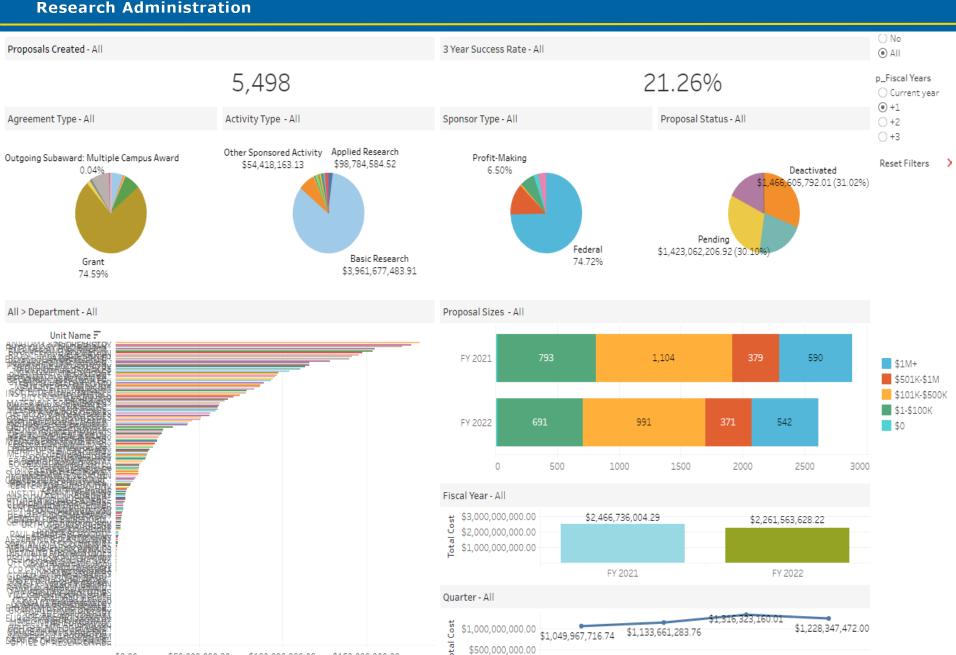














Questions?

Barbara Inderwiesche barbara.i@uci.edu
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