

Quarterly Research Administration Meeting

March 12, 2025



Agenda

- Welcome
- Federal Updates
- C&G Accounting Update
- Research Security & Engagement (RSIE) Procedures
- New DURC Requirements
- ERA Support
- Huron Status Update
- Q&A and Closing



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Spring 2025 QRAM: Federal Update

Agenda

UCI

- Impact of Federal Executive Orders and Directives
 - Federal Funding Update
 - NIH Supplemental Guidance Notice
 - Recommendations for Federal Proposals
 - Guidance for Active Awards
 - Resources
- Data Management and Access Practices NIH Genomic Data
- Questions



Federal Funding Update

OMB Funding Freeze Memo

- January 29, 2025
 - OMB rescinded a memo issued two days earlier that called for a funding freeze on thousands of federal programs, pending administrative review.
- February 3, 2025
 - A Temporary Restraining Order (TRO) filed stating the administration cannot "pause, freeze, impede, block, cancel, or terminate" its obligations to provide federal financial assistance, "except on the basis of the applicable authorizing statutes, regulations, and terms."
 - Judge affirmed that any further award actions must follow the notice and procedural terms of each award under this TRO.

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Federal Funding Update

Gap in NIH and NSF Awards

- NIH: January 30 February 13, 2025
- NSF: February 4 February 14, 2025
- UCI has now started receiving new NIH and NSF awards with federally negotiated indirect cost rates.

Department of Energy Award

Most recent award received on January 16, 2025.

NIH No-Cost Extension

• NIH reinstated the automatic first no-cost extension option in eRA Commons on February 12, 2025.

Federal Payment Systems

- ACM\$, ASAP, and other federal payment systems are online.
- Contracts and Grants Accounting are actively drawing down funds.



NIH Supplemental Guidance Notice

NIH Supplemental Guidance Notice (NOT-OD-25-068)

- Issued on February 7, 2025
 - Introduced a new standard indirect cost rate of 15% across all NIH grants
 - Intended to replace previously negotiated rates
 - Applicable to both new and existing NIH awards
- TRO Issued on February 10, 2025
 - In response to Emergency Motions filed by several Plaintiff States, including the State of California, and the Association of American Universities
 - Temporarily halts the implementation, application, and enforcement of the new standard indirect cost rate
 - Previously negotiated indirect cost rates will remain in effect for the time being

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NIH Supplemental Guidance Notice

UC's Announcement:

 UC supports the California Attorney General's lawsuit challenging NIH's new policy to cap facilities and administration cost rates at 15% for NIH-funded grants.

Council on Government Relations (COGR):

- COGR has expressed deep concern over NIH's decision, highlighting that such a cap could severely hinder lifesaving research and innovation.
- Emphasizes that indirect costs are integral to conducting world-class research and that this policy change contradicts existing laws and policies.

Collaborative Responses:

- Several associations, including the American Council on Education (ACE), Association of American Universities (AAU), and Association of American Medical Colleges (AAMC), have joined COGR in opposing the cap.
- These organizations have released statements underscoring the detrimental effects the policy could have on research and institutional operations.



Recommendations for Federal Proposals

Federal Funding Opportunities

- Proposals may be submitted to available federal funding opportunities as long as federal submission systems remain operational.
- Federal agency proposal review timelines may be delayed due to agency-specific implementation plans and funding guidelines.
- Check program websites and funding opportunities regularly for changes in deadline dates and/or program requirements to ensure compliance.

Proposal Compliance Tips

- Review new versions of funding opportunities carefully to ensure compliance.
 While changes are often highlighted, not all wording changes may be explicit.
- Sign up for federal agency alerts, if available.
- Office of Research leadership will continue to share information with staff and the campus.



Guidance for Active Awards

Active Awards Performance

- Performance on active awards can continue if obligated funds are available and a stop-work or termination order has not been issued by the agency.
- Notices of new, continuing, or supplemental funding may be delayed.
- NIH employees were informed on Monday, February 24th that Federal Register notices for study sections run by its Center for Scientific Review will start being permitted again.
- Awards currently under negotiation may be placed on hold until further notice by the funding agency.

Communication with Program Officers

- Pls should stay in contact with their program officers, if possible.
- Keep updated on any changes or instructions from the funding agency.



Guidance for Active Awards

Monitoring Updates and Communications

- Monitor updates from federal agencies, the Office of Research, and Sponsored Projects for updates on funding or compliance requirements.
- If any award notifications or other agency communications are received, including "Stop-Work" or "Termination" Orders, please promptly forward them to awards@research.uci.edu.

Expenditure Guidelines

- Pls should not adjust spend rates for extramurally funded research projects.
- Expenditures should proceed under standard conditions.

Resources



- UCI Office of Research: https://research.uci.edu/impact-of-federal-executive-orders-and-directives-on-federal-grants-and-contracts/
- UCI Federal Updates: https://uci.edu/federal-updates/
- UCI Library News & Newspapers: https://guides.lib.uci.edu/news
- UCOP: https://www.universityofcalifornia.edu/federal-updates
- COGR: https://www.cogr.edu/2025-administration-transition-information-resources
- COGR Summary of Executive Orders: https://www.cogr.edu/cogr-summary-executive-orders

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NIH GDS Policy

The National Institutes of Health (NIH) has introduced important revisions to its Genomic Data Sharing (GDS) Policy, which took effect on January 25, 2025.

Strengthened Cybersecurity Guidelines: Researchers who access de-identified human genomic data must ensure that their institutional systems adhere to the National Institute of Standards and Technology (NIST) Special Publication 800-171 cybersecurity framework.

Institutional Compliance Measures: Institutions are to assess both existing and new projects to ensure they align with the updated requirements.

UCI Compliance Strategy: A Plan of Action and Milestone (POAM) has been created to outline our approach for meeting these compliance standards. The Office of Information Technology (OIT) and the Office of Research are collaborating with other stakeholders, including Principal Investigators and senior leadership, to execute the POAM.

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Contracts & Grants Accounting

Alice Han

Director, Extramural Funds Accounting



Agenda

- Contracts and Grants Accounting staff update
- C&G accounting cash draw update
- C&G accounting training



Staff Update

 Effective 1/27/2025: New Contracts and Grants Accountant IV-Vicky Lu



C&G accounting cash draw update

- All Federal grants- weekly cash draw
- Federal flow through awards-monthly



Key Actions for Departments

- Review and Reconcile Expenses Regularly: Ensure frequent and consistent reconciliation to stay ahead of any discrepancies.
- Identify and Correct Errors Promptly: Catch errors early and make necessary corrections as soon as possible to maintain accurate records.
- Process Expenses Without Delay: Avoid holding expenses—C&G
 Accounting processes cash draws strictly based on the ledger.



C&G Training

COURSE #1 (CGS 1) Introduction to Fund Management *Thursday, April 24, 2025, 10:30 a.m. – 12 p.m.*

COURSE #2 (CGS 2) Direct vs. F&A

Tuesday, April 29, 2025, 10:30 a.m. – 12 p.m.

COURSE #6 (CGS 6) Ledger Reading and Award Closeout Thursday, May 01, 2025, 10:15 a.m. – 12 p.m.

Available in UCLC as an e-Course

COURSE #3 (CGS 3) General Error Correction (GEC)/Cost Transfers

COURSE #4 (CGS 4) Payroll Certification

COURSE #5 (CGS 5) Cost Sharing



Questions?



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Research Security & International Engagement (RSIE) Procedures

Nadia Wong

Research Compliance & Outreach Manager



KR Proposal Development- Personnel Tab

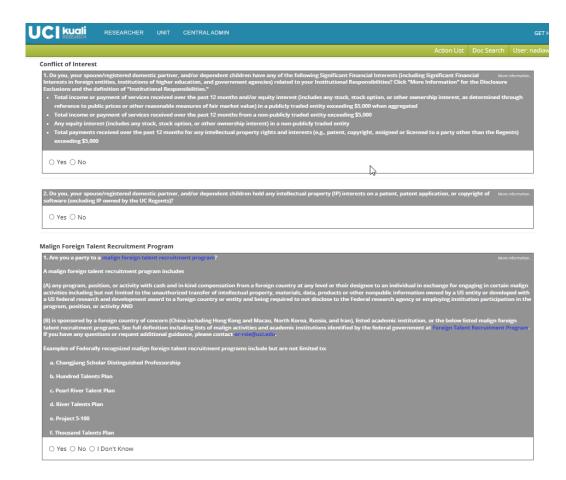
It is important to assign roles appropriately to avoid unnecessary delays.

Federal Proposal Review Does the Federal sponsor/prime sponsor require a biographical sketch from this individual?	Conflict of Interest Is the individual an "Investigator" (responsible for the design, conduct, or reporting of the project)?	KR PD Personnel Role(s) Which KR PD Personnel Role should be used for that individual?
Yes	Yes	Principal Investigator, PI/Contract, PI/Multiple, Co-PI, or Key Person
Yes	No	Other Significant Contrib. (Contributor)
No	Yes	Federal sponsor/prime sponsor with COI Policy (PHS, DOE, NSF, and NASA): Investigator
No	Yes	Federal sponsor/prime sponsor without a COI Policy: Do not include the individual in the KR PD Personnel tab
No	No	Do not include the individual in the KR PD Personnel tab



KR Federal Disclosure and Certification

- Replaced KR COI Annual Disclosure on 10/31/24
- Satisfies:
 - Conflict of interest disclosure requirements for PHS, NSF, DOE, and NASA
 - Confirmation of no participation in malign foreign talent recruitment program
- Must be completed prior to proposal submission
- Still required annually

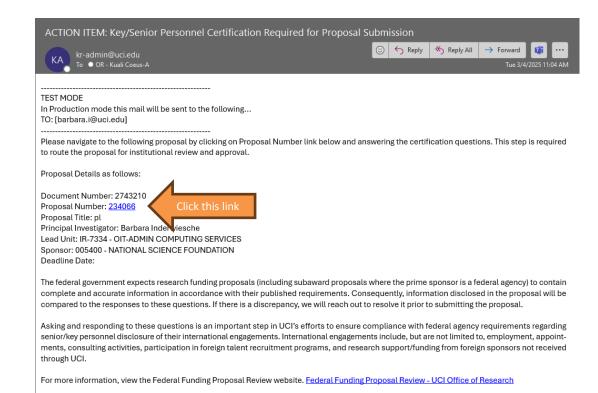


Note: If a researcher responds "Yes" or "I Don't Know" to the MFTRP question, RSIE will contact them



KR PD Personnel Certification Questionnaire Email

 Each researcher identified as requiring the submission of a biographical sketch will receive an email with a unique URL to the Personnel Certification Questionnaire regarding their foreign affiliations and activities





KR PD Personnel Certification Questionnaire

oposal Development	
Certification for Barbara Inderwiesche	
oposalif: 234066 let: pl Barbara Inderwiesche ad Unit: IR-7334 onsor: NATIONAL SCIENCE FOUNDATION addine Date:	
Print	
e you employed by a foreign entity? ①	
Yes	
No	
e you a consultant (paid or unpaid) for a foreign entity? "Consultant" broadly refers to an individual that provided or provides a paid or unpaid service to a foreign entity whether or not there is a written agreement for the service performance.	med. ①
Yes	
O No	
you hold an academic appointment (including an honorific or ment-based title) or have an academic affiliation with a foreign entity? 🛈	
) Yes	
O No	
e you currently participating in, have you been accepted into, or do you have an application pending with a foreign government talent recruitment program or a similar program? ①	
) Yes	
O No	
ies any proposal to a foreign government research funding entity include support or funding for you that will not be received through UCI? ①	
Yes	
O No	
you have research support or funding from a foreign government research funding entity that was not received through UCI? ①	
) Yes	
No.	

- OR uses this information to verify that the biosketch and other/current & pending support documents are accurate
- This questionnaire is collected for each new federal or federal flow through proposal prior to proposal submission



Certification Questionnaire Name Poll

Which name do you prefer?

- 1. RSIE Biosketch and Research Support Verification
- 2. RSIE Federal Proposal Questionnaire



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New Dual Use Research of Concern (DURC) Requirements

Christine Tafoya, Biosafety Officer

Grace J. Park, Research Engagement & Compliance Director



Definitions

- Dual use research of concern (DURC) is life sciences research that has the greatest potential for generating information that could be readily misused to threaten public health and national security
- Pathogen with pandemic potential (PPP) is a pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans
- Pathogen with enhanced pandemic potential (PEPP) is a type of pathogen with pandemic potential (PPP) resulting from experiments that enhance a pathogen's virulence or disrupt the effectiveness of pre-existing immunity



New Policy

- New Policy <u>USG Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential</u> and <u>Implementation Guidance</u>
 - NIH Implementation effective May 6, 2025
- Combines USG DURC Policy (2012), Institutional DURC Policy (2014), and P3CO Framework (2017)
 - Category 1 Research (DURC)
 - Category 2 Research (PEPP)



Category 1 (DURC)

- Current DURC review process has narrower scope of review
 - Limited to life sciences research that involves 15 named agents and toxins and 7 categories of experiments
- New policy scope
 - DURC review expanded to any federally funded research with infectious agents
 - Agent scope is broader: includes numerous agents divided into Category 1 and Category 2
 - 12 types of experiments between Category 1 and 2 agents



Category 1 (DURC)

 Does your research use any of the select agents and toxins AND will your research reasonably anticipated to result in one or more of the 9 experimental outcomes?

Agents and Toxins?

<u>Select agents and toxins</u>; OR Risk Group 4 agents (<u>NIH Guidelines Appendix B-IV</u>); OR

BSL3/BSL4 agents and Risk Group 3 agents (NIH Guidelines Appendix B-III)

Experimental Outcomes?

- Increased transmissibility
- Increased virulence
- Increased stability/dissemination
- Altered host range
- Decreased diagnostic detectability
- Increased resistance to treatments
- Disrupted pre-existing immunity
- Enhanced host susceptibility



Category 2 (PPP)

- Research involves, or is reasonably anticipated to result in:
 - A Potential Pandemic Pathogen (PPP);
 - The development, use, or transfer of a Pathogen of Enhanced Pandemic Potential (PEPP); or
 - An eradicated or extinct PPP that may pose a significant public health threat



Category 2 (PPP)

 Does your research use any PPP or PEPP or an eradicated or extinct PPP AND your research reasonably anticipated to result in one or more of the 4 experimental outcomes?

Agents?

- A Pandemic Potential Pathogen (PPP), meaning a highly transmissible pathogen capable of causing severe illness; OR
- A Pathogen with Enhanced Pandemic Potential (PEPP), which is a PPP modified to increase transmissibility or virulence; OR
- An eradicated or extinct PPP that poses a public health threat, regardless of whether the experiment enhances the PPP.

Experimental Outcomes?

- Enhanced transmissibility
- Enhanced virulence
- Enhanced immune evasion
- Reconstitution of an eradicated or extinct pathogen



DURC Review Process

Current

- PI notifies the IRE of possible DURC research
- IRE determines if research is DURC and develops draft risk mitigation plan
- Institution communicates with funding agency to finalize acceptable plan

<u>New</u>

- At proposal stage: PI conducts initial assessment and notifies IRE and agency confirming whether research may be within scope
- At JIT: Agency notifies PI and institution regarding initial assessment
- IRE confirms PI's initial assessment of whether research is DURC and if so, submits assessment and draft risk mitigation plan to agency for final review and approval
- Agency review, evaluates, verifies, and finalizes IRE's mitigation plan



Additional New Requirements

- Provide education and training on research oversight for Category 1 or Category 2 research for individuals conducting life sciences research that may be within the scope of this Policy.
- Annual DURC review
- More defined requirement for documentation of risk assessment, risk mitigation plans
- Considerations for communications of research data, transfer of technologies, public perception



UCI Implementation

- Communication to PIs with currently approved Biological Use Authorizations
- DURC IRE
- Coordinating comments to UC DURC policy
- Amending KR DURC gating questions
- Revising UCI DURC website
- Developing UCI DURC training



Questions?

Christine Tafoya, Biosafety Officer, tafoyac1@uci.edu

Grace J. Park, Research Engagement and Compliance Director, parkgi@uci.edu



Breakouts



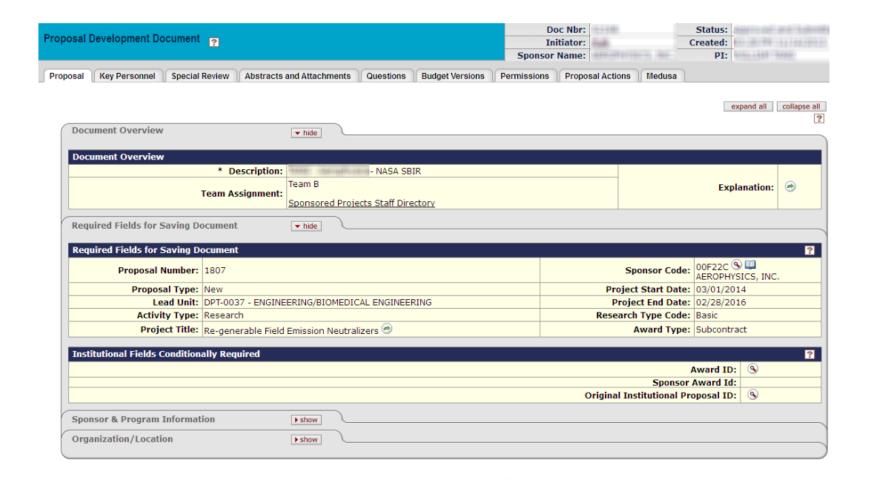
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ERA Support Request Form







ERA Support – "Back in the Day"

- 2012 System Support
 - -Kuali Coeus (KC) Proposal Development
 - -NIH eRA Commons
 - NSF Fastlane
 - -Handful of small external systems
 - Grants.gov SF424 Forms



ERA Support – Today

Kuali Research

Proposal Development

Institutional Proposal

Negotiations (Federal / Non-Federal Teams)

Negotiations (Clinical

Trials)

Negotiations (Material Transfer Agreements)

Award

Subaward

Unfunded Agreements

Expanded NIH ERA

Commons

ASSIST

RePORTer

NSF Fastlane

Research.gov

SciENcv

MyNCBI

Research Management

System (RMS)

IACUC

ULAR

Researchers

Cayuse 424

FileNet Document Storage

for IRB and SPA

IRB / HSCRO web

applications and legacy

database

DocuSign

Cognos

Tableau

ServiceNow

Other Decision Support Tools such as BLISS and

DW Query

EBRAP

American Heart

Association

DARPA BAA Portal

Dept. of Justice GMS

System

DTRA Proposal Submission

System

eGMS (NEH)

FedConnect

tFermiLab Supplier Portal

GRaNTS (Dept of Water

Resources)

Grants Solutions (CDC)

Grants.gov

HRSA EHBS

Laura & John Arnold

Foundation

NASA Nspires

NIH ASSIST

NOAA Grants Online

PAMS (Dept. of Energy)

PCORI

ProposalCentral

SAM.gov

SAMS Domestic (Dept. of

State)

Visual Compliance

WAWF (DoD)

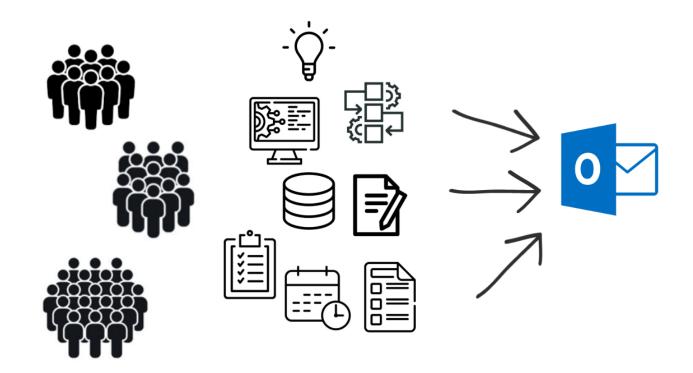
Over 50+

systems / portals /

websites / online platforms!

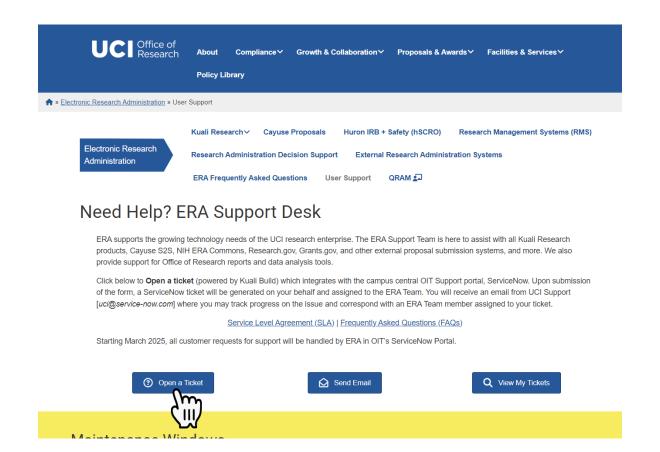


ERA Support - Background





ERA Support - Opportunity

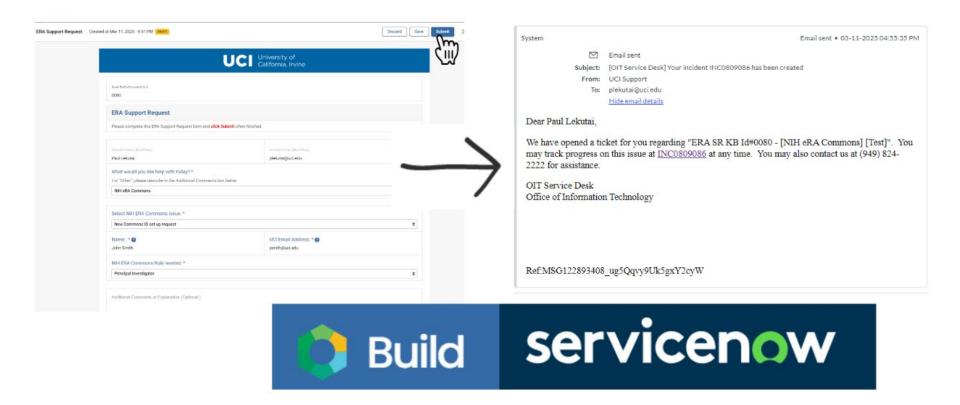






ERA Support - Simple Process

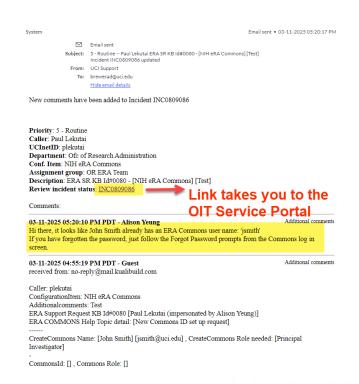
Step 1. You complete and submit the form. You get an email.

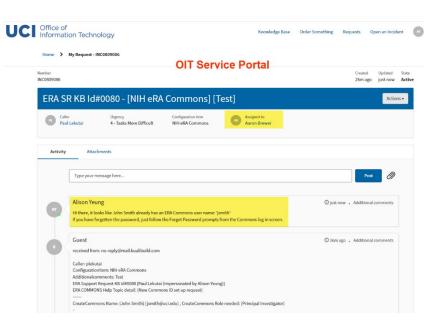




ERA Support - Simple Process

Step 2. ERA person is assigned and contacts you as needed. You can respond by email or in the OIT Service Portal.

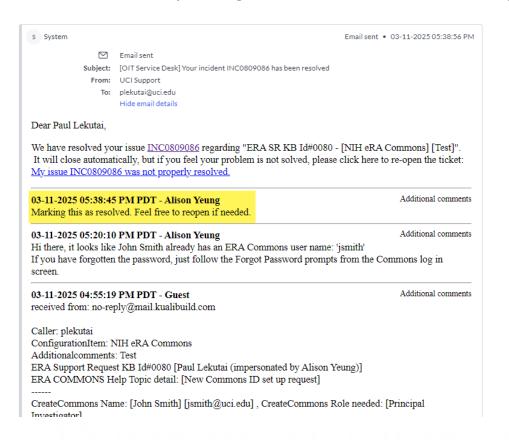






ERA Support - Simple Process

Step 3. Problem solved. (You get a "Resolved" email.)





ERA Support - Solution





Accessible to anyone at UCI





ERA Support - Solution

Ability to quickly add new help topics

Tracking and transparency

Knowledge management





What You Need to Do

https://research.uci.edu/electronic-researchadministration/user-support/

Other ways to get to the page:

- Link from the email announcement
- Go to <u>research.uci.edu/era</u> and click on User Support
- Look for it in our signature line
- Email <u>era@research.uci.edu</u>





Soft Launch Period – March 2025

- First step: Try using the Support Request Form!
- Now through March 31, if you email us at <u>era@research.uci.edu</u>, we'll create the ticket for you.

Official Cutover – April 1, 2025

After <u>April 1</u>, we'll direct you to use the form.
 (We will still monitor our email.)





The New Process

- Customer creates ticket and receives an email from ServiceNow
- Ticket is assigned to ERA Team member
- ERA Team member works on the ticket
- Communicates with you as needed in ServiceNow
 - You will receive emails with the comments
- ERA Team member resolves the ticket
 - Resolution will be in the ticket (you will get an email)
 - You have two days to re-open a ticket if the resolution isn't satisfactory
 - Ticket will be marked as 'Closed'



Agenda

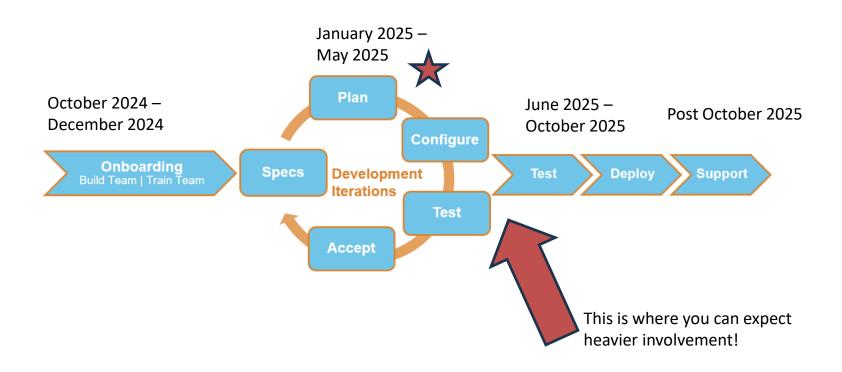
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Huron IRB and Safety at UCI Update



Overall Timeline

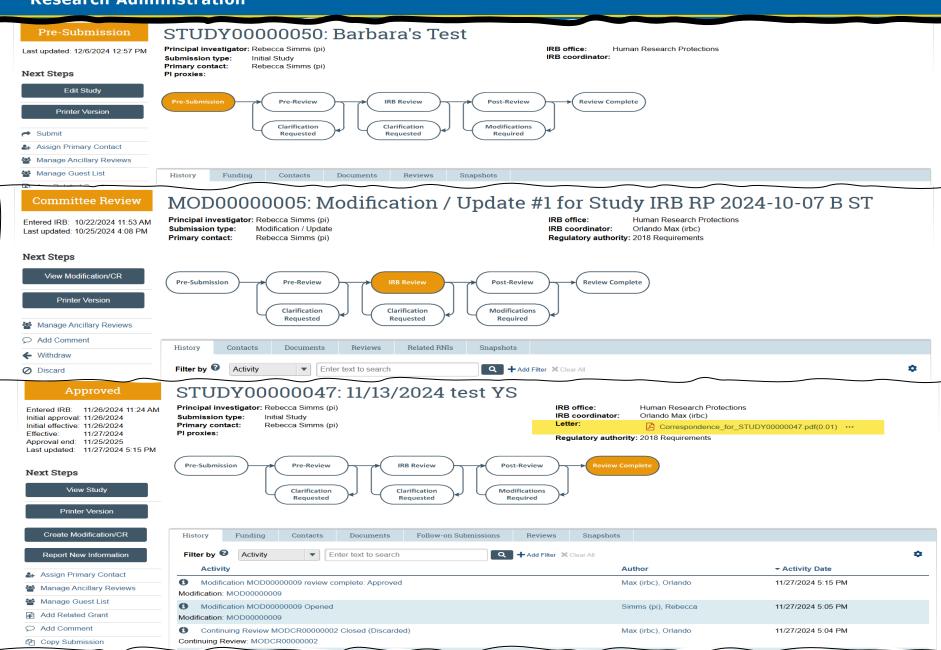




Progress

- Initiated Project Champions meetings
- Zot IRB and Zot hSCRO lead the polls
- Published website: https://research.uci.edu/irbhscro/
- Concluded major requirements gathering
- In our first development cycle; unit testing
- Verified HR, sponsor and org hierarchy feeds are working
- Beginning discussions on functional data mapping and migration
- Federated login for Safety UCSB researchers
- Starting to discuss go live dates in September or October







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