Spring QRAM

April 8, 2026

Agenda

- ***ERA Updates***
- C&G Accounting Updates
- UCI Buy +
- RSIE Updates
- HRP Updates
- SPA Updates

ERA Updates

Barbara Inderwiesche

Director, Electronic Research Administration

Abstract Text Requirement in PD

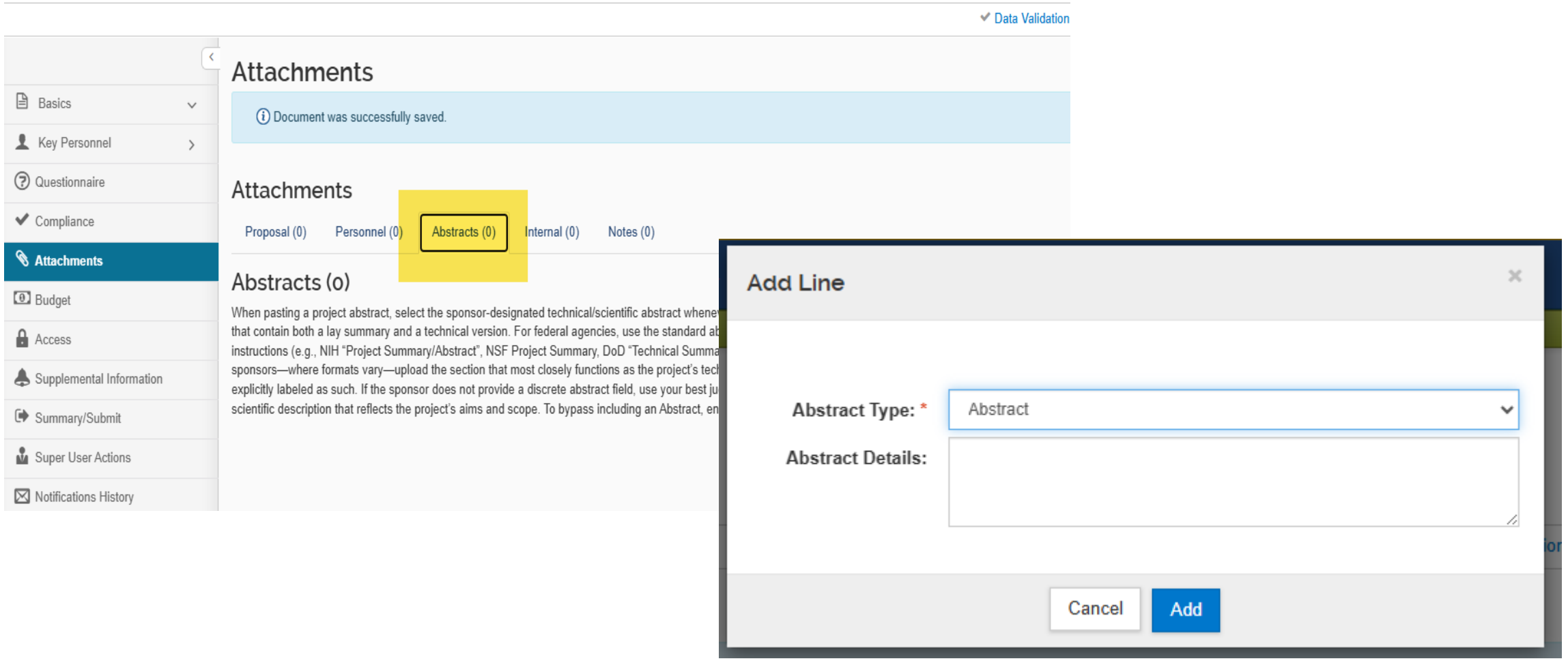
- As of March 26, 2026, entering text in the Abstract field in KR PD is required.
  - Applies to all proposals at any stage of workflow. If it hasn't been Approved and Submitted by SPA, it's required!
- Why?
  - To assist UCI leadership in identifying interdisciplinary research opportunities, match researchers with funding prospects, and connect researchers with potential extramural sponsors.

https://news.research.uci.edu/uncategorized/kr-proposal-development-update-abstract-entry-required-starting-march-26/

Abstract Text Requirement in PD

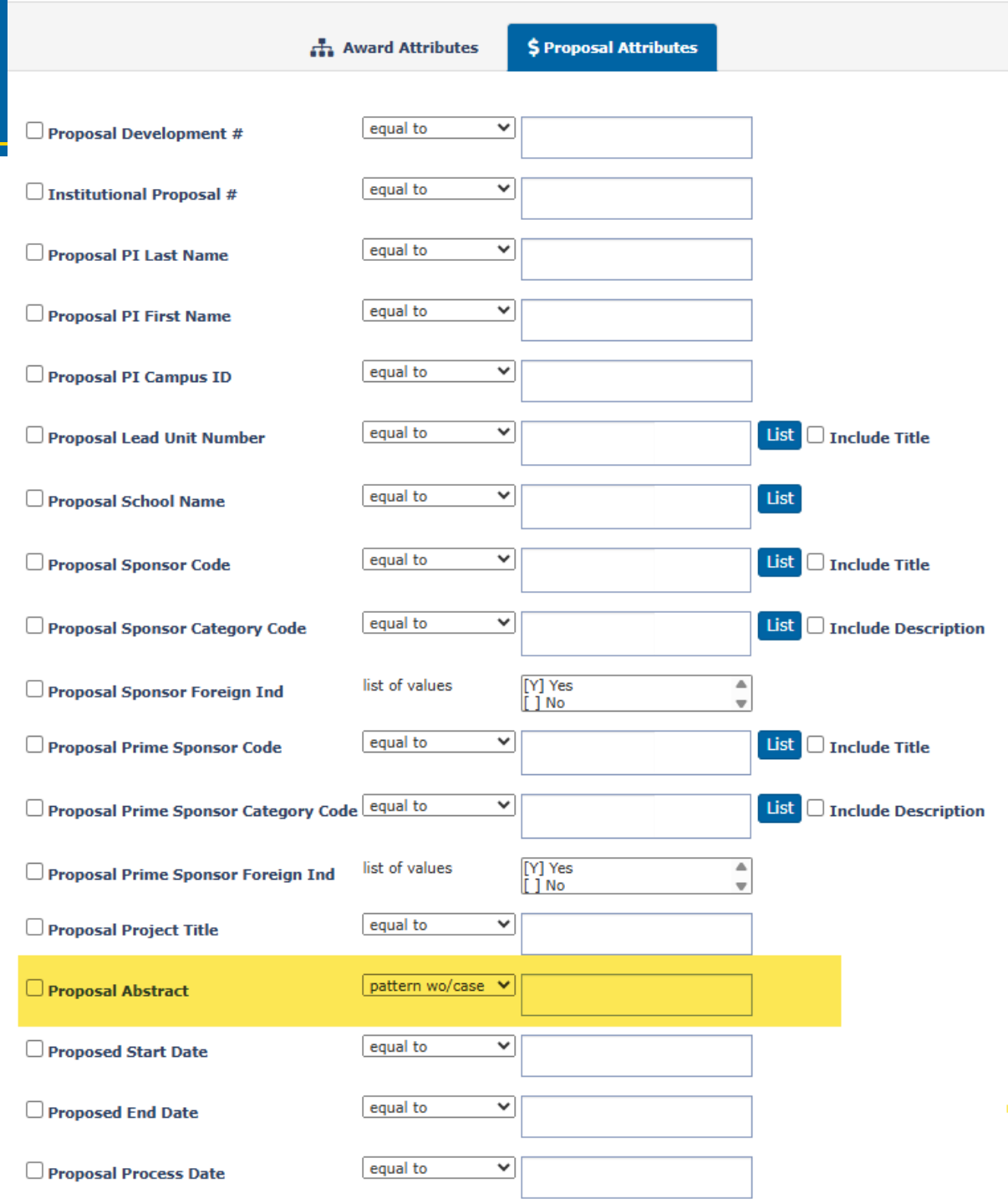
- What to include?
  - When copying and pasting a project abstract, select the sponsor-designated technical/scientific abstract whenever one is provided, including for applications that contain both a lay summary and a technical version.
  - For federal agencies: Use the standard abstract section identified in the sponsor's instructions (e.g., NIH "Project Summary/Abstract", NSF Project Summary, DoD "Technical Summary").
  - For foundations and other non-federal sponsors—where formats vary: Copy and paste the section that most closely functions as the project's technical or scientific abstract, even if it is not explicitly labeled as such.
  - If the sponsor does not provide a discrete abstract field, use your best judgment to identify and copy and paste the concise scientific description that reflects the project's aims and scope.

Abstract Text Requirement in PD



Contracts/Grants Ad Hoc Query

- Proposal Abstract is available to query through Contracts/Grants Adhoc Query as a Proposal Attribute.



KR Downtime

- AWS ACDC Migration
  - Migrating UCI's on-prem environments to Amazon Web Services (AWS).
- Kuali Research (KR) production servers are scheduled to migrate on **Thursday, 04/16/2026**.
- ***KR will be completely off-line from 8AM-5PM***.
- Does not affect external systems: Cayuse, NIH eRA Commons, Research.gov etc.
- For emergency deadlines, contact your Contract & Grant Officer.

Zot!Portal Decommission

Zot!Portal Decommission

- Current Zot!Portal is end of life so OIT is migrating to a new, homegrown version
- Cutover: Fall 2026
- New ZotPortal:

  https://web.communications.uci.edu/portal/
- Decision Support Tab is moving to UCI Decision Support:

  https://app.powerbi.com/groups/me/apps/ff644baa-17f3-4b5a-a43c-601de1728c85/reports/52e43e85-42a7-4ac2-bb32-78a12ca22ba3/a96887f90756fee980aa?ctid=68d4533c-eae6-4833-99cc-7a9704ac870b&experience=power-bi

Faculty/Staff Holidays

See the full list of campus holidays for faculty members and staff.

UCPath

Visit the UCPath Website to view pay statements and more.

ZotGPT

Get free access to popular AI chatbots and other AI tools – log into ZotGPT.

Find UC Irvine Web Resources

Select a functional area below to find applications, tools, and other web resources available to the UC Irvine community.

Applications

Find links for most of the apps and tools available to UC Irvine employees.

Decision Support

Your single source for all UC Irvine reports and dashboards related to finance, research and other topics.

Finance

Access the Kuali Financial System and other tools useful to the campus financial community.

Human Resources

Find useful links from Human Resources and the Employee Experience Center.

Research

Access Kuali Research (KR) and other resources from the Office of Research.

Research

Search for a link (Ctrl+K)

Popular searches: Action List | Award | COI | IRB | Negotiation

Kuali Research Proposal

Create a Proposal
Initiate a new development proposal document

Cayuse 424
Access to Cayuse 424

Development Proposal Search
Search for development proposals

Institutional Proposal Search
Search for institutional proposals

Institutional Review Queue
Check institutional proposals status

Sponsor Code Search
Search for active sponsor codes. Email era@research.uci.edu for sponsor code requests

Research News

Fed Update: COGR News Digest
April 7, 2026

FW: Virtual Workshop – Prompting and Practical AI Use Cases in Research Administration – Unlimited Additional Logins
April 6, 2026

Spring QRAM Agenda and Zoom Info
April 2, 2026

Google.org Impact Challenge
April 2, 2026

Fed Update: COGR News Digest
April 1, 2026

ZOT IRB & ZOT hSCRO

ZOT IRB Portal
Submit or check the status for an IRB protocol

ZOT IRB User Guide
Onine user guide for ZOT IRB

ZOT hSCRO Portal
Submit or check the status for an hSCRO protocol

ZOT hSCRO User Guide
Onine user guide for ZOT hSCRO

Research Protections +

Human Research Protections (IRB)

UCI Office of Research
Research Administration

UC Irvine | UCI Decision Support | Data updated 3/20/26

Search

File | Share | Export | Explore | Subscribe | Set alert | ... | Copilot

UCI Decision Support

- UCI About Decision Support
- UCI Decision Support
  - UCI Decision Support
  - Decision Support Favorites
- UCI Data Loading Dashboard

UCI Decision Support

UCI Decision Support

KFS | Office of Research | UCPath

Filters

Subject	Section	Report	Purpose
Office of Research			
	Award Activity	Awards by Campus Area	Provides year over year award funding totals summarized by school.
		Awards by Source by Campus Area	Provides yearly award funding totals summarized by funding source.
		IT Security Term Award Lookup (BNPR-OR-020)	Provides a self-service award lookup report where the IT Security term is included.
		Multi-Year Funded Awards (BNPR-OR-090)	Provides a self-service report for the COI team to review Multi-year funded awards.
		Personnel Awards Credit by Role	Provides funding totals for all active awards grouped by researcher role.
	DWQuery	Contracts/Grants Ad Hoc Query	Provides a self-service reporting tool of OR Contracts & Grants.
		Instructions on using Contracts/Grants Ad Hoc Query	A PDF User Guide on utilizing the DWQuery ad-hoc report of OR Contracts & Grants.
	Negotiations Activity	Material Transfer Agreement Count (INPR-OR-020)	Provides counts for Material Transfer Agreements based on a date range, broken down by Incoming/Outgoing/Mutual.
		Negotiation Activities	
		Non-Funded Agreements (BNPR-OR-100)	Provides a list of Non-Funded agreements based on various parameters like negotiator, agreement type and award action.
	Negotiations Activity (Material Transfer Agreement (MTA) Negotiations)		
	OR Special Reports		
	OR Special Reports (Conflict of Interest)		
	Proposal Activity		

Quick Links

- Award Transaction Summary (ATS) Search
- CG Accounting Workload Report
- Institutional Review Board Fees
- Institutional Review Queue
- Kuali Research
- Office of Research Home Page
- Subaward Transaction Summary (STS) Search
- Tutorial Verification Search

Questions?

Agenda

- ERA Updates
- ***C&G Accounting Updates***
- UCI Buy +
- RSIE Updates
- HRP Updates
- SPA Updates

Contracts & Grants Accounting

Alice Han
Director, Extramural Funds Accounting

Agenda

- Reminder for annual Contracts and Grants deficit clearing
- C&G accounting training

Annual Contracts and Grants Deficit clearing

March 31

- Awards that ended in the prior fiscal year and remain in deficit (270+ days) will be identified
- Deficit clearing process begins in April

April 15

- Assistant Deans receive a list of awards requiring deficit clearing

April 30

- All deficits will be cleared by transferring direct expenses on C&G accounts to their continuation accounts.

May 31

- Detailed report of transfers and impacted continuation accounts will be provided to each school
- Ensures all entries are completed before fiscal year-end (June 30)

- Annual Contracts and Grants Deficit Clearing Process

C&G Training

- **COURSE #1 (CGS 1) Introduction to Fund Management**

Tuesday, April 28, 2026, 10:30 a.m. – 12 p.m.

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

Thursday, April 30, 2026, 10:30 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**
- **COURSE #6 (CGS 6) Ledger Reading and Award Closeout**

Questions?

Agenda

- ERA Updates
- C&G Accounting Updates
- ***UCI Buy +***
- Research Security
- HRP Updates
- SPA Updates

UC Irvine

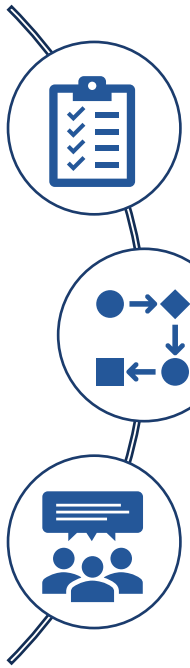
Division of Finance & Administration | With U • For U

UCIBuy+ Implementation Overview

QRAM Presentation

April 7, 2026

Agenda



Project Overview & Status

System Overview and Workflow

Support Resources & Discussion

Project Overview & Status

UCIBuy+ is Launching April 13th, 2026

Project Review

Migrating Existing Functionality
KFS (REQ/PO) ➔ Jaggaer (UCIBuy+)

Goal 1: Improve Customer Experience
Simplify forms, clarify compliance, and increase workflow visibility.

Goal 2: Increase Process Efficiency
Speed up processing, automate & standardize steps, lower transaction costs.

Goal 3: Maximize Procurement Savings
Prioritize use of contracted suppliers.

New Features

- Expansion of UCIBuy to process non-catalog REQs and POs
- User-friendly interface improvements (advance catalog shopping, hints and tips, simplified order entry)
- Enhanced ability to track REQ & PO requests
- Allow REQ send back for corrections instead of canceling
- Incorporate compliance requirements in REQ workflow
- Transition exceptional PALCard approvals to Jaggaer

Unaffected Systems & Documents

- PALCard Reconciliation (PCDO); Contract Authoring & Execution; Equipment Inventory Management
- Payment of invoices in KFS; PREQ, CM, DV, TEM*
- Vendor onboarding (PaymentWorks)*
- Interdepartmental/Unit Facilities Recharges*

**Owned by Accounting & Fiscal Services*

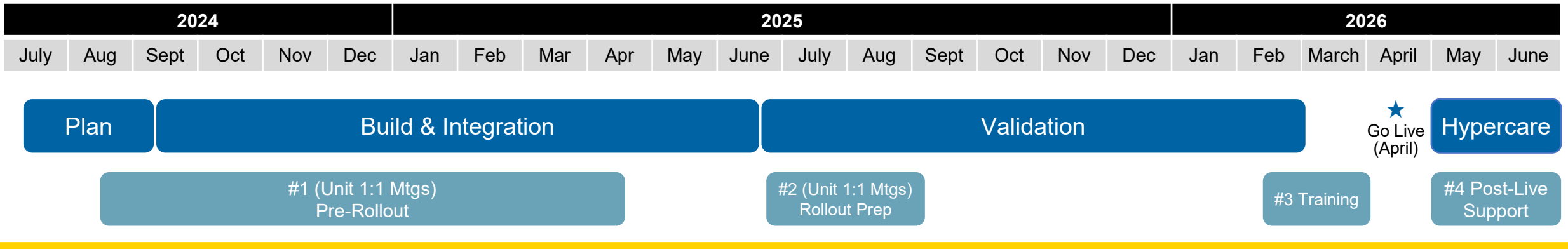
Project Timeline At-A-Glance

Discovery ✓
April 1-Aug. 31, 2023

Analysis ✓
Sept. 5-Nov. 30, 2023

Design ✓
Dec. 1-June 30, 2024

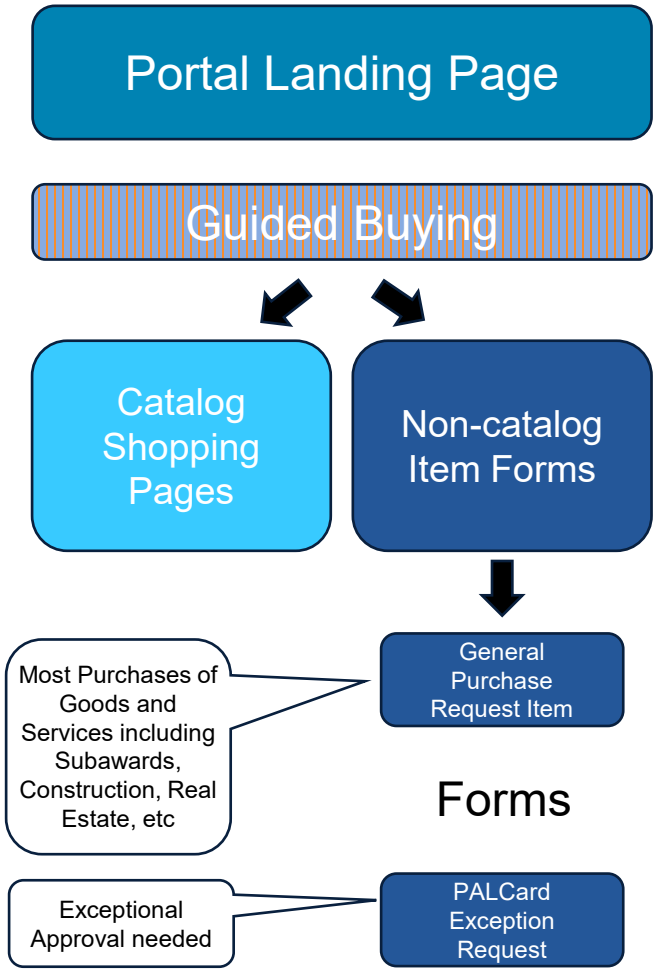
Implementation
July 1, 2024-Present



System Overview and Workflow

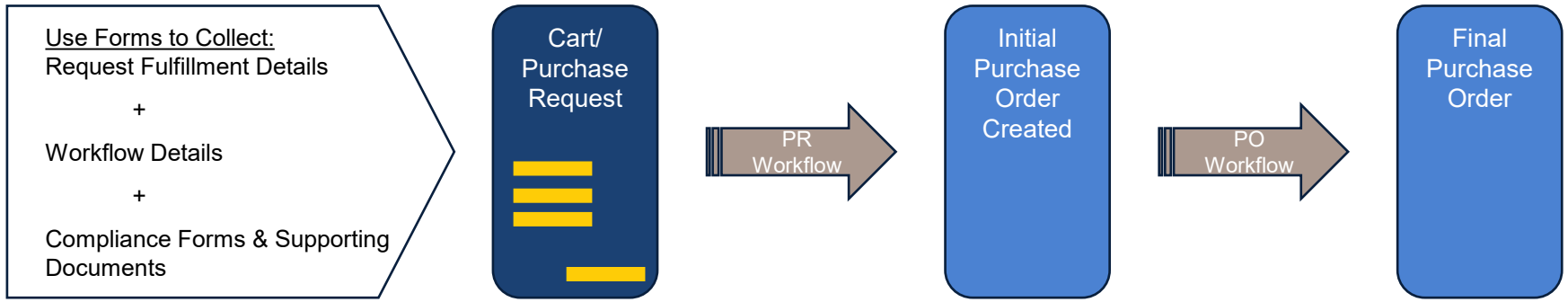
Enhanced Visibility and Efficient Compliance Tracking

UCIBuy+ Purchase Data Flow

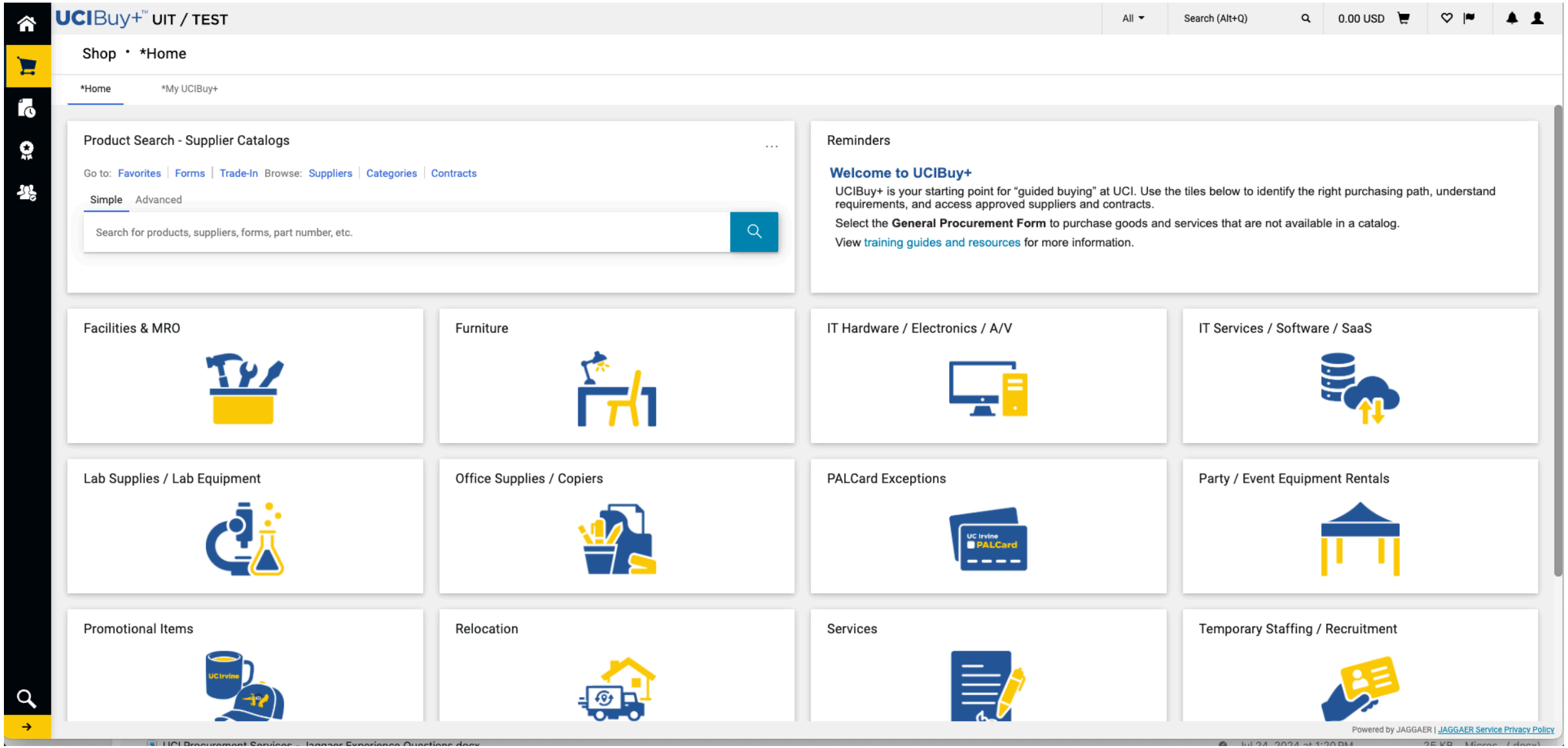


Request Form Features:

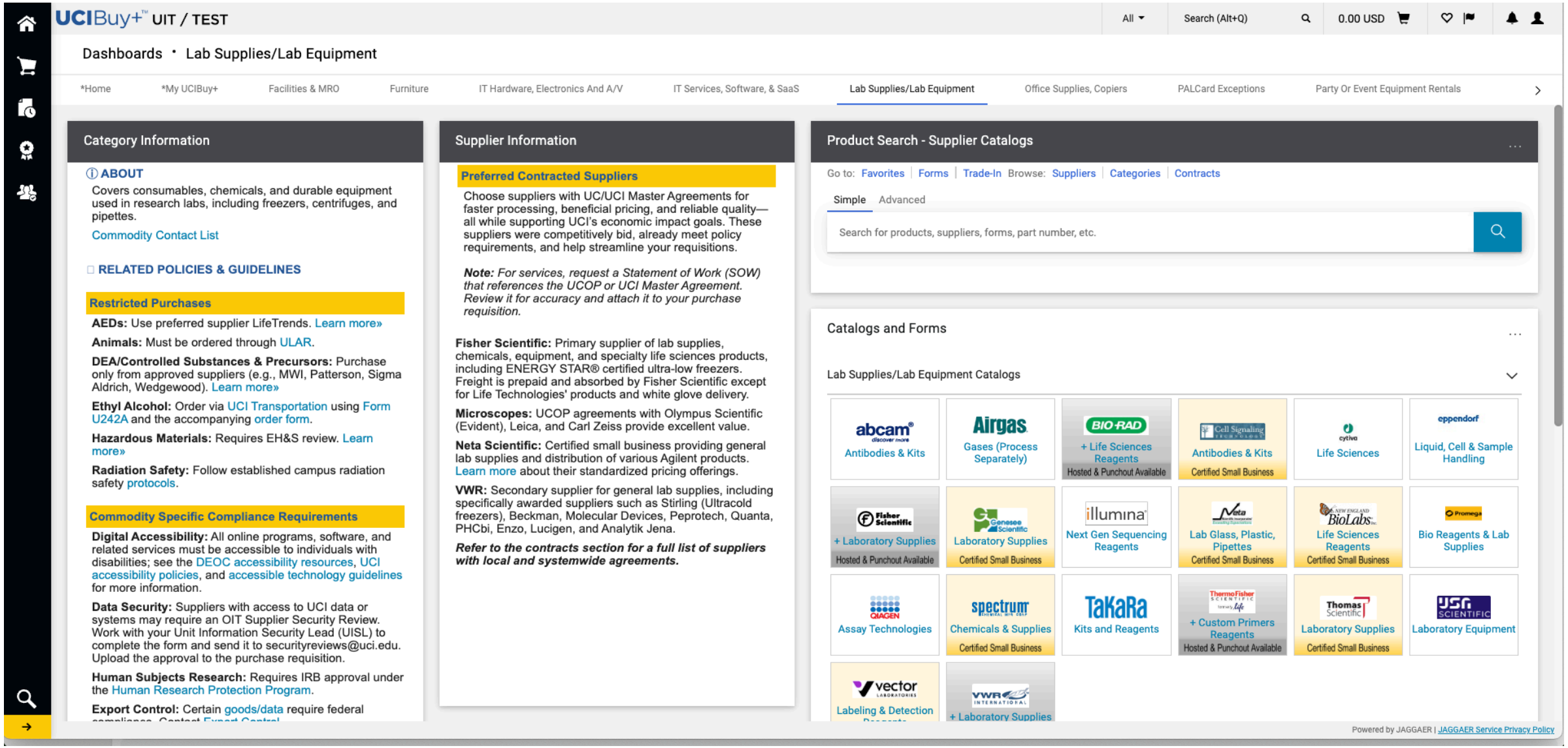
- Request Forms guide end users to capture fulfillment details and supporting documents required for workflow & compliance
- Workflow steps will be dynamically added to the purchase request based on information available on the order



UCIBuy+ Landing Page

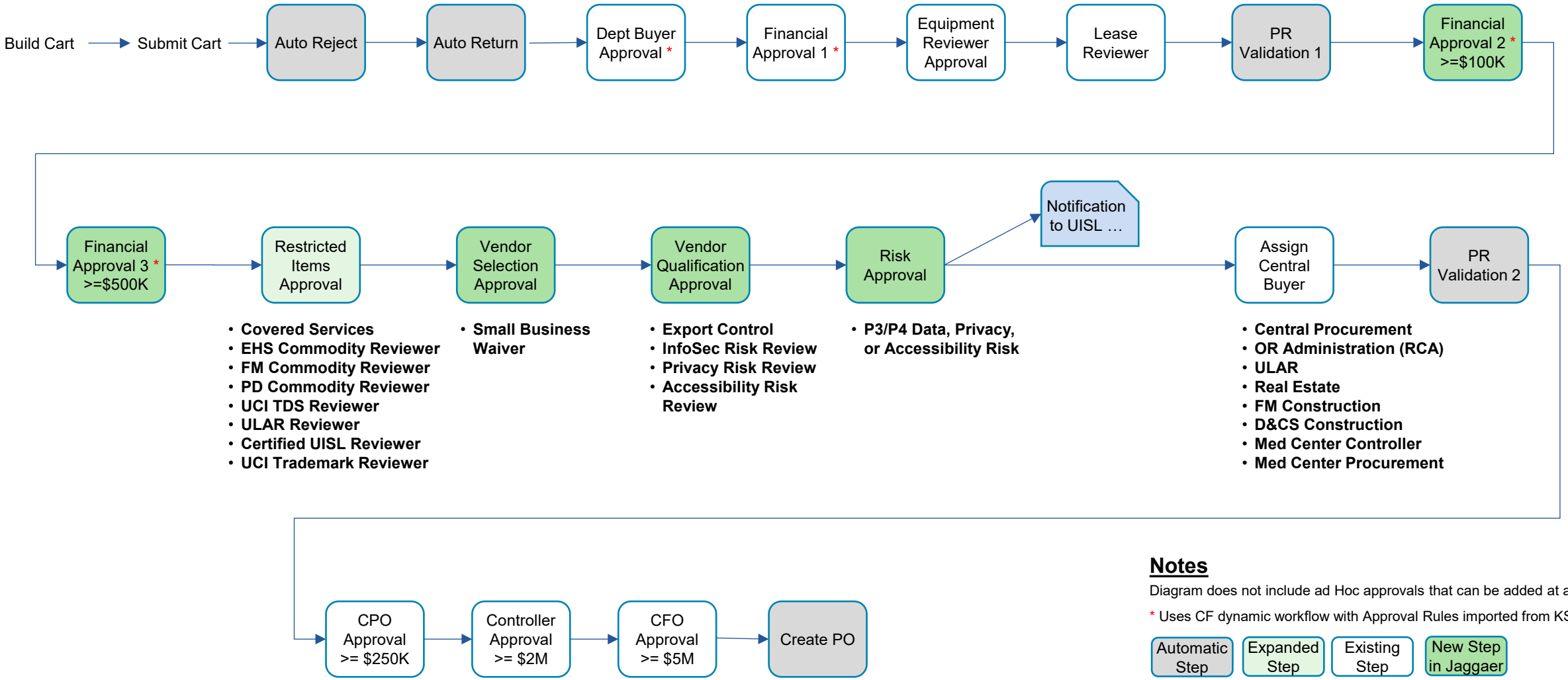


UCIBuy+ Dashboard



Future State Purchase Requisition (PR) Workflow

Each step is conditional and will only trigger if criteria is met based on PR data and type



Notes

Diagram does not include ad Hoc approvals that can be added at any step

* Uses CF dynamic workflow with Approval Rules imported from KSAMS roles

Automatic Step | Expanded Step | Existing Step | New Step in Jaggaer

Support Resources

Webpages, FAQs, Instructional Guides, Virtual Office Hours

UCI Procurement Services

Visit >

System Transition/Cutover Planning

Project	UCIBuy+ Roles & Workflow	Project Resources
Explore	Explore	Explore

Start Closing Out Existing POs

As we get closer to the go-live date, more details will be shared outlining the tasks required to transition from the current system to the new one. In the meantime, begin closing out POs with remaining balances for goods or services that have already been received. Instructions are available starting on page 10.

For additional information regarding System Transition/Cutover Planning, review the Frequently Asked Questions (FAQs) below.

System Downtime

UCIBuy and KFS purchasing functions will be temporarily unavailable or limited from March 30 through April 10 as we transition to UCIBuy+. PALCards will remain operational during this period. Other KFS functionality such as general error corrections (GEC), payment of invoices, travel & event management (TEM), will continue to be available during the downtime period. See the calendar below for details.

UCIBuy+ Instructional Guides

These guides will continue to be updated through project go-live. Do not download and save local copies. Always ac page to ensure you have the latest version.

- UCIBuy+ (A): Basics/Navigation
- UCIBuy+ (B): Requisitioner - Submitting an Order
- UCIBuy+ (C): Departmental Buyer - Completing the Non-Catalog Requisition
- UCIBuy+ (D): Typical Purchasing Scenarios
- UCIBuy+ (E): Special Scenarios

Review the guides below for instructions and information on UCIBuy+ functionality.

UCIBuy+ (A): Basics/Navigation

Whether new to the system or in need of a quick refresher, these resources support the UCIBuy+ site and its features from finding items and managing carts to tracking purcha settings.

Job Aids	Audience
1. Navigating the Basics of UCIBuy+	Central Buyers, Department B Requisitioners, Restricted Item
2. How to Access the Dashboard	Central Buyers, Department B Requisitioners, Restricted Item
3. How to Access the Action Items.	Central Buyers, Department B Requisitioners, Restricted Item
4. How to Search for Catalog Items in UCIBuy+	Department Buyers, Requisitio
5. How to Save Personal Favorites	Department Buyers, Requisitio
6. Managing UCIBuy+ Carts	Department Buyers, Requisitio
7. How to Assign, Return, and Reject a Purchase Requisition	Central Buyers, Department B Restricted Items Approvers
8. How to Assign a Cart	Department Buyers, Requisitio
9. How to Check Purchase Order (PO) Status	Central Buyers, Department B Requisitioners, Restricted Item

FAQs

1. What happens to existing purchase orders and recurring POs?
2. How will PO amendments be processed after UCIBuy+ goes live?
3. Will suppliers transfer to the new system?
4. Will the payment process change?
5. What happens to requisitions or POs in draft or pending approval when downtime begins?
6. Can I submit requests for mission critical or emergency purchases during downtime?
7. When will requisition, PO, and approval processing resume?
8. How should departments prepare for downtime?

Hypercare Support

Enhanced Helpdesk Support

What changes during hypercare:
- Extended hours – 8 hrs a day coverage
- Additional staffing – project core team and Jaggaer solutions consultants will provide L1/L2/L3 support
- Priority handling for hypercare-related tickets

Process specifics:
- Dedicated ticket queue/category
- Faster Service Level Agreements (SLAs)
- Escalation rules

Resources:
- Helpdesk staff
- Functional SMEs
- Technical support teams

Daily Office Hours

Purpose:
- Provide real-time support for users
- Reduce ticket volume
- Accelerate issue clarification

Structure:
- Schedule (2 daily 2-hour blocks)
- Format (Zoom drop-in)
- Facilitators (core team members +functional SMEs)

Use cases:
- “How do I…” questions
- Minor issues / confusion
- Quick triage before ticket submission

Monitoring Command Center

Purpose:
- Daily central monitoring and coordination
- Ensure rapid resolution of critical issues
- Maintain shared visibility

Attendees:
- Helpdesk support team
- Project core team
- Functional SMEs
- Jaggaer solution consultant

Agenda:
- Review open issues (by severity)
- Identify blockers
- Assign owners
- Track trends and risks

Questions/Discussion

Agenda

- ERA Updates
- C&G Accounting Updates
- UCI Buy +
- ***RSIE Updates***
- HRP Updates
- SPA Updates

Research Security and International Engagement Reminders and Updates

Grace Park
Director, Research Engagement and Compliance

Nadia Wong
Research Compliance and Outreach Manager

NSF Recipient Required Documents

- NSF issued a requirement for institutions to maintain supporting documentation for all senior/key personnel, including copies of current and pending:
  - Contracts
  - Grants, and
  - Any other agreements specific to:
    - Foreign appointments
    - Employment with a foreign institution
    - Participation in a foreign talent recruitment program, and
    - Other information reported as current and pending (other) support
- Please inform your NSF researchers that they should start collecting these documents, which NSF may request.
- Office of Research is developing tools and procedures to meet this requirement. Please stay tuned for updates.

DOD Risk Matrix

Updated the Department of Defense Decision Matrix to Inform Fundamental Research Proposal Mitigation Decisions for DOD funded projects on or after March 9, 2026.

Reminder

- **Malign Foreign Talent Recruitment Programs (MFTRP):** DOD continues to prohibit funding any covered individual who is participating in an MFTRP.
  - If a senior/key person may be participating in an MFTRP, contact RSIE immediately.

DOD Risk Matrix

Changes

- **Expansion of Prohibited Entities**: The Department of Defense (DOD) broadened the list of entities they do not allow their funds to be used in collaboration with or using equipment from for fundamental research.
  - Indicate foreign collaborators in the proposed DOD funded project in your KR Development Proposal to ensure that RPS screening occurs.
  - Vendors of equipment purchased through Procurement will be screened through the onboarding vendor review process by Accounts Payable.
- **Mitigation Measures Now Required:** Previously, certain factors were used to identify *expected or suggested* mitigation measures. Those factors have been combined into one new category, Mitigation Measures Required. As a result of the change, requests for Risk Mitigation Plans should increase.
  - Review the updated matrix
  - Contact RSIE immediately for assistance if a researcher receives a request for a Research Security Risk Mitigation Plan

NIH Monetary Donations

- When a monetary donation is used to fund an individual's research, then it must be disclosed in their Other Support, regardless of whether an individual or an entity provided the funds. This also includes situations when UCI received the monetary donation and then allocated some of those funds to an individual's research program.
  - Uses not considered funding research (not Other Support disclosure): facilities maintenance, staff salaries, capital improvements, purchasing a new computer, general operations, construction of a new building
- NIH example scenarios

Updated RSIE Biosketch and Research Support Verification on 4/30

- Will affect senior/key personnel listed in all in progress proposals who have not completed the KR PD questions and all new federal proposal initiated on or after this date

- **Key Changes**
  - New screening question allows individuals who have no current or pending engagements, positions, affiliations, etc. with a country of concern to submit after completing this question. Previously, these individuals had to answer all six questions before submitting.
  - RSIE Biosketch and Research Support Verification form now asks only about current or pending engagements, positions, affiliations, etc. with a country of concern. Previously, the form asked about all foreign current or pending engagements, positions, affiliations, etc.

New Questions

- Do you have any engagements with an individual or entity involving a Country of Concern (China including Hong Kong and Macau, Iran, Russia, Saudi Arabia, United Arab Emirates, Qatar, and North Korea)?
  - **If No – click "Certify Answers" and then "Save and Exit" to submit the completed questionnaire**
  - **If Yes – display next 4 questions:**

New Questions

2. Do you currently hold any paid or unpaid positions including: employment, consulting, academic appointments (honorific or merit based), or affiliations with any entity associated with a Country of Concern?

3. Are you currently participating in, have you been accepted into, or have submitted an application to a foreign talent recruitment program or a similar program from a Country of Concern?

4. Are you listed on any pending proposals or currently active awards submitted to a sponsor based in a Country of Concern that will NOT be received through UCI?

5. Do you receive or will receive other research support including in-kind contributions (e.g., personnel support such as staff, students, visiting scholars, office or laboratory space, equipment, supplies, data, materials, etc.) from an individual and/or entity involving a Country of Concern?

If you respond “yes” to any of the last four questions, additional questions will display. For additional information, please review the Printable Questions Reference.

Research Security Training

- Research security training is mandated for individuals involved in federally funded research by CHIPS & Science Act of 2022 and National Security Presidential Memorandum 33 designed to ensure awareness of security risks and policies
- To comply with this requirement, it is important that all senior/key personnel or covered individuals are listed as personnel in KR PD. For more information on who needs to be listed, visit https://research.uci.edu/rsie/fedprop-review/.

Current Research Security Training Requirements

Implemented research security training requirement for the following federal and federal flow-through proposals for all listed senior/key personnel in KR PD

- Department of Energy- effective May 1, 2025
- National Science Foundation- effective October 10, 2025

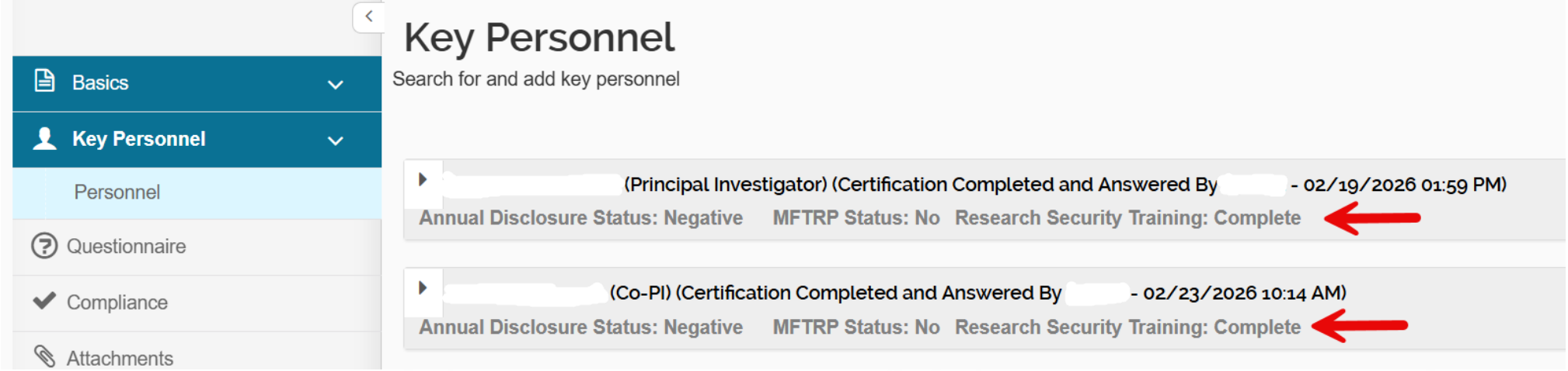
Remaining Federal Agencies

All federal and federal flow-through proposals submitted on or after May 25, 2026 will require all listed senior/key personnel in KR PD will be required to complete research security training within the last 12 months prior to proposal submission

- The Research Security at the University of California module (30-40 minutes) is already available. Please encourage your researchers to complete the training if they haven't already

Remaining Federal Agencies

Beginning May 26, 2026, initiators will be able to see the current Research Security Training statuses of the listed senior/key personnel on the proposal. The status must say complete for the proposal to be submitted.



Questions?

Agenda

- ERA Updates
- C&G Accounting Updates
- UCI Buy +
- Research Security
- ***HRP Updates***
- SPA Updates

UC Irvine

FDA Guidance on Safety Reporting

Rachna Basu, MS, CCRP, CIP
Assistant Director, Human Research Protections

Outline

- New guidance documents from FDA
- Which safety reports need to be reported and to whom?
- Determining what events are reportable
- Implications of the guidance on sponsors, investigators, and IRBs

New FDA guidance

FDA release two final guidance in December 2025 on Safety Reporting:

- Investigator Responsibilities Safety Reporting for Investigational Drugs and Devices and
- Sponsor Responsibilities - Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies

The 2025 guidance replaces the previous FDA guidance from 2009 and 2012

New FDA guidance on Safety Reporting

Who does what? - Clarified

The guidance reinforces that:

- The **sponsor** is in the best position to review safety information and identify which safety related events should be reported in real time to the FDA and the **Investigator**

- The **Investigator** is the responsible party for **reporting unanticipated problems to the IRB** (21CFR312.66)

Sponsor Responsibilities

- Submit IND safety reports to FDA and investigators only when events are:
  - Serious
  - Unexpected
  - Suspected adverse reactions (evidence suggests causality)
- Sponsors must be more cognizant about what is labeled as an “IND Safety Report” and what is sent to the FDA and investigator in real time compared to annual reporting.

Investigator Responsibilities

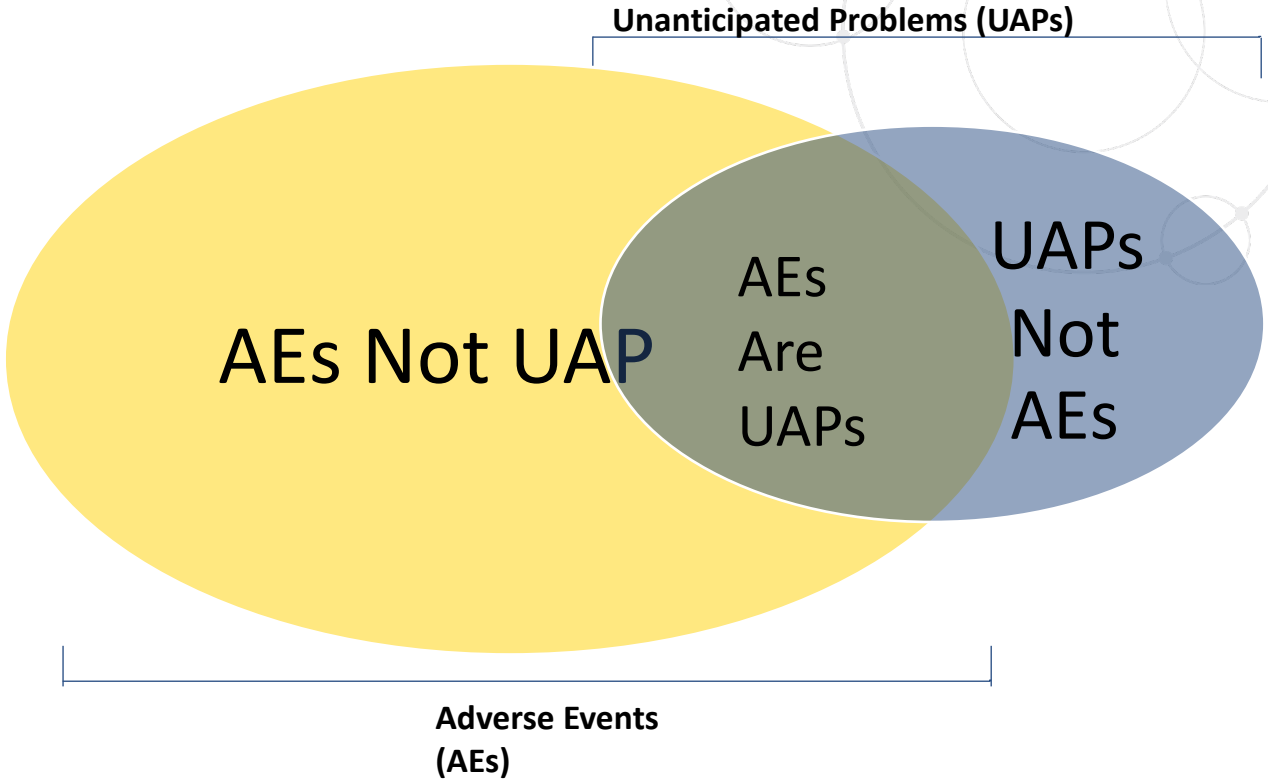
- **Responsible party** for reviewing IND safety reports and reporting unanticipated problems to the IRB
- Must review overseeing IRBs reporting requirements before submitting IND safety reports to the IRB
- Under FDA regulations (21 CFR 312 and 56), the following must be treated as Unanticipated Problems involving risks to participants or others (UPIRTSOs) and therefore, require IRB review:
  - i. Serious and unexpected suspected adverse reactions
  - ii. Findings from other clinical studies suggesting significant risk
  - iii. Animal or in vitro findings suggesting human risk
  - iv. Increased rate of serious suspected adverse reactions
  - v. All SAEs in IND-exempt BA/BE studies
  - vi. All Unanticipated Adverse Device Effects (UADEs)

These categories are explicitly identified in FDA regulations (21CFR312.32(c)(1) and do not represent a new or expanded UAP definition.

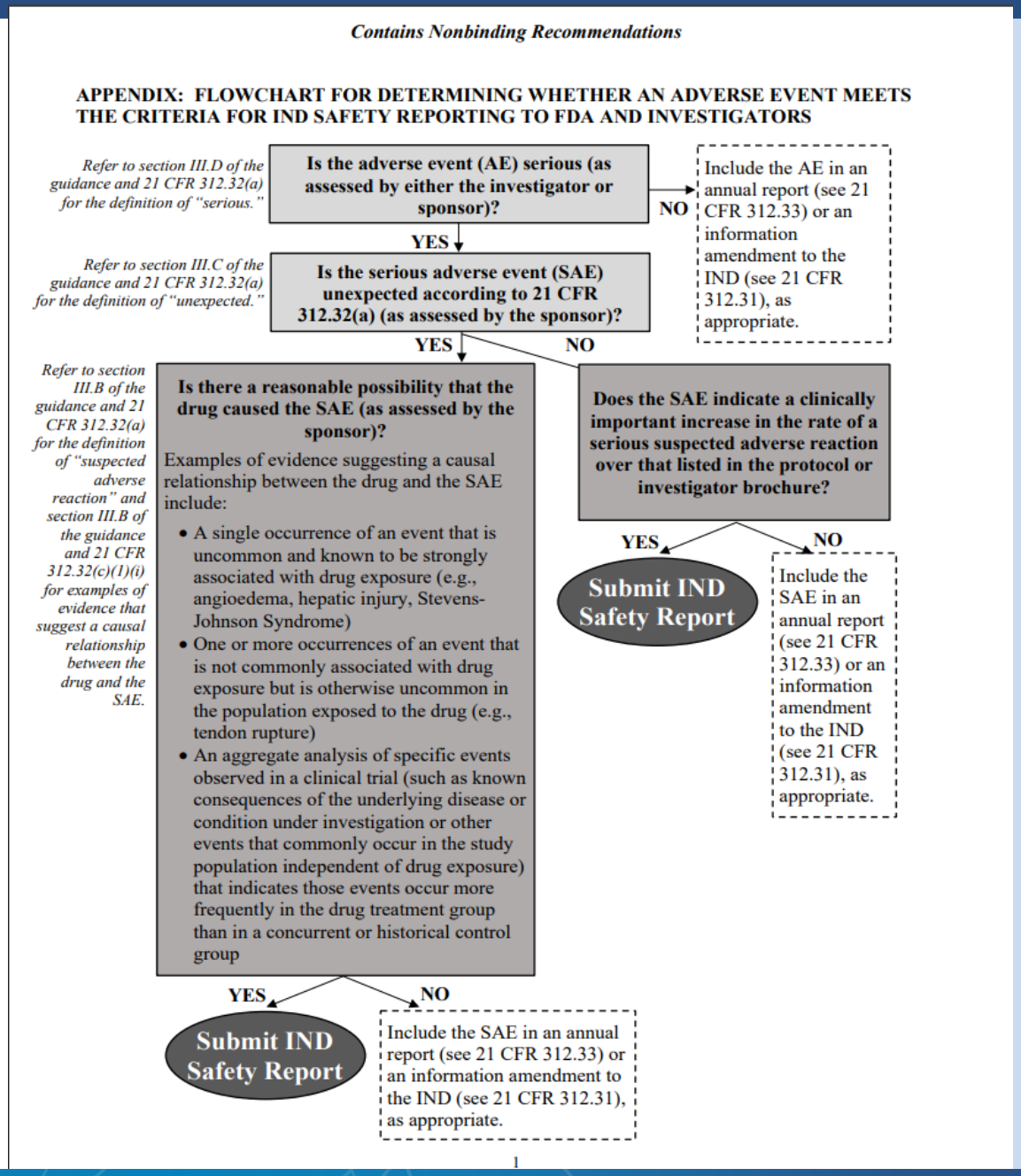
IRB/HRPPs Responsibilities

- Defining what constitutes a UAP and how those determinations will be reported to the appropriate institutions and the regulatory authorities.

- **Three Questions:**
  - Is the AE unexpected?
  - Is it related or possibly related to participation?
  - Does the AE suggest that research places subjects or others at a greater risk of harm.



- Decision tree: Appendix (page 43 of Sponsor Responsibilities guidance)



Contains Nonbinding Recommendations

APPENDIX: FLOWCHART FOR DETERMINING WHETHER AN ADVERSE EVENT MEETS THE CRITERIA FOR IND SAFETY REPORTING TO FDA AND INVESTIGATORS

Refer to section III.D of the guidance and 21 CFR 312.32(a) for the definition of "serious."

Is the adverse event (AE) serious (as assessed by either the investigator or sponsor)?

NO → Include the AE in an annual report (see 21 CFR 312.33) or an information amendment to the IND (see 21 CFR 312.31), as appropriate.

YES ↓

Refer to section III.C of the guidance and 21 CFR 312.32(a) for the definition of "unexpected."

Is the serious adverse event (SAE) unexpected according to 21 CFR 312.32(a) (as assessed by the sponsor)?

YES ↓

Refer to section III.B of the guidance and 21 CFR 312.32(a) for the definition of "suspected adverse reaction" and section III.B of the guidance and 21 CFR 312.32(c)(1)(i) for examples of evidence that suggest a causal relationship between the drug and the SAE.

Is there a reasonable possibility that the drug caused the SAE (as assessed by the sponsor)?

Examples of evidence suggesting a causal relationship between the drug and the SAE include:

- A single occurrence of an event that is uncommon and known to be strongly associated with drug exposure (e.g., angioedema, hepatic injury, Stevens-Johnson Syndrome)
- One or more occurrences of an event that is not commonly associated with drug exposure but is otherwise uncommon in the population exposed to the drug (e.g., tendon rupture)
- An aggregate analysis of specific events observed in a clinical trial (such as known consequences of the underlying disease or condition under investigation or other events that commonly occur in the study population independent of drug exposure) that indicates those events occur more frequently in the drug treatment group than in a concurrent or historical control group

YES → **Submit IND Safety Report**

NO → Include the SAE in an annual report (see 21 CFR 312.33) or an information amendment to the IND (see 21 CFR 312.31), as appropriate.

NO ↓

Does the SAE indicate a clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure?

YES → **Submit IND Safety Report**

NO → Include the SAE in an annual report (see 21 CFR 312.33) or an information amendment to the IND (see 21 CFR 312.31), as appropriate.

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Additional Updates & Reminders

Beverley Alberola, CIP
Senior Director, Human Research Protections

Changes Involving Biomedical Consent

Policy Update:

- **HRP-090 SOP - Informed Consent Process for Research has been updated to incorporate the following changes:**
  - **Removal of prior requirement that only a US licensed medical doctor or a US licensed nurse practitioner may request to finalize informed consent when a protocol involves an investigational drug, device or surgical procedure.**
    - The IRB will continue to review the education, experience and training from each investigator to determine if the individual is suitable to finalize informed consent.
    - Principal Investigators (PIs) are reminded to provide sufficient information on the qualifications and proposed roles of each member of the research team.
  - **Additional requirement for greater than minimal risk research that involves the application of an investigational drug, device, or surgical procedure.**
    - **The protocol must include an individual authorized by the institution to independently prescribe the drug, device or perform the surgical procedure on the protocol. This individual, as approved by the IRB, must also be listed on the consent form and available to finalize consent.** The PI is responsible for determining whom (in addition to themselves, if appliable) on their study team meets this definition.

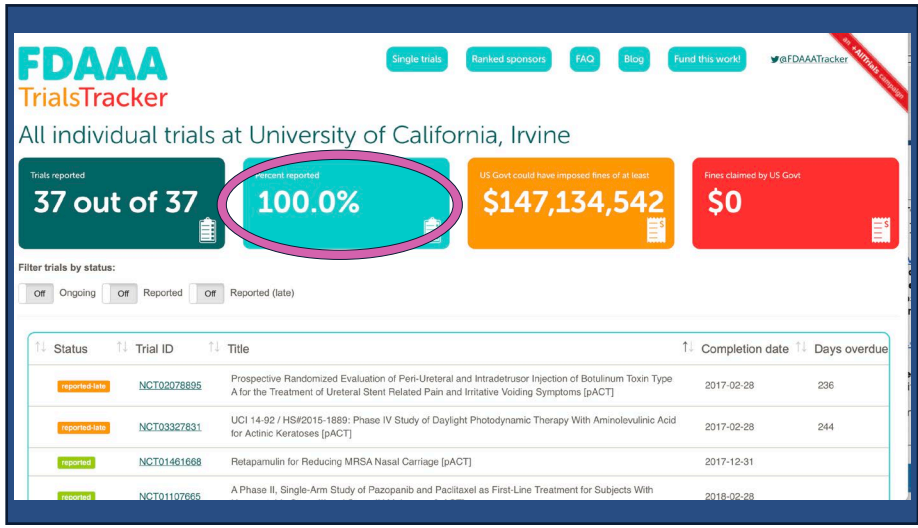
Changes Involving Biomedical Consent

Consent Update:

- *A new section* added to the consent template titled OTHER RESEARCHERS PROVIDING MEDICAL MANAGEMENT OF SUBJECTS will provide a space to specify those investigators providing medical care of subjects, as required by the protocol and available to finalize consent. ***In accordance with the biomedical consent template, only list those that will finalize consent!***
- *Updated text* added to the COMPENSATION section in accordance with the One Big Beautiful Bill Act increasing the IRS reporting threshold from $600 to $2000 per calendar year.
- *Updated text* added to the WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY? section, Option 1. PIs are reminded to review this section, along with the complete consent document to ensure text reads accurately and consistently. The PI must ensure that the consent process is comprehensive and subjects are sufficiently informed. ***We are currently further updating the costs section – stay tuned!***

Reminder: ClinicalTrials.gov

- If human subject research is subject to ClinicalTrials.gov, registration and submission of results is required.
- Where the protocol is investigator initiated and / or the UC Irvine Principal Investigator (PI) holds the Investigational New Drug (IND) the UC Irvine PI is responsible.
- A ClinicalTrials.gov Registration Decision Tool is available on the HRP ClinicalTrials.gov webpage. The decision tool combines the registration requirements for Food and Drug Administration (FDA), National Institutes of Health (NIH), and International Committee of Medical Journal Editors (ICMJE). When accessing the tool for the first time, you will be directed to log in with your UCInetID. Use this resource and work closely with HRP colleagues to help determine if your research is subject to ClinicalTrials.gov. There is no need to submit this form.
- For those that have registered, PIs must submit results as required. Look at Clinicaltrials.gov or use the FDAAA TrialsTracker to confirm you have submitted results.
- **There are significant implications to the PI and UC Irvine, if results are not submitted:**
  - Approximate **$15,000 per day** penalty against responsible parties who fail to comply with registration and/or results submission requirements
  - In relation to federally funded studies, **withholding of remaining or future grant funds** from a grantee for failure to submit clinical trial registration and results information.



Great job UC Irvine!

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Questions?

Agenda

- ERA Updates
- C&G Accounting Updates
- UCI Buy +
- RSIE Updates
- HRP Updates
- ***SPA Updates***

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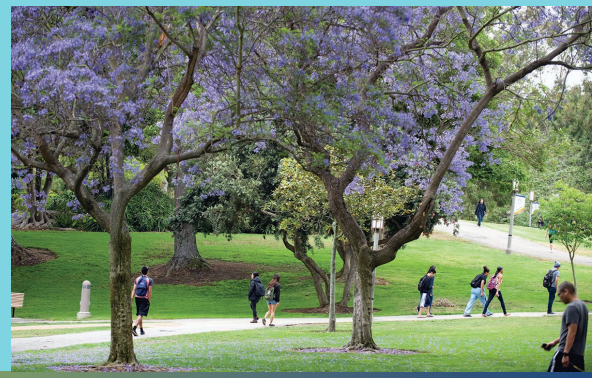
QRAM - Sponsored Projects

8 April 2026

Federal Landscape Update

Agenda

- Industry Clinical Research Contracting
- Revised National Institutes of Health (NIH) Grants Policy Statement
- NIH Guide Notices
- Implementation of the Commons Forms
- NIH Collaborative International Research Project
- Indirect Costs
- General Reminders & Updates



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Industry Clinical Research Contracting

UC Irvine

Industry Clinical Research Contracting — Team Restructure

To **better serve our partners and improve operational efficiency**, the Industry Clinical Research Contracting team has been restructured with a **more efficient and customer-centric infrastructure**.

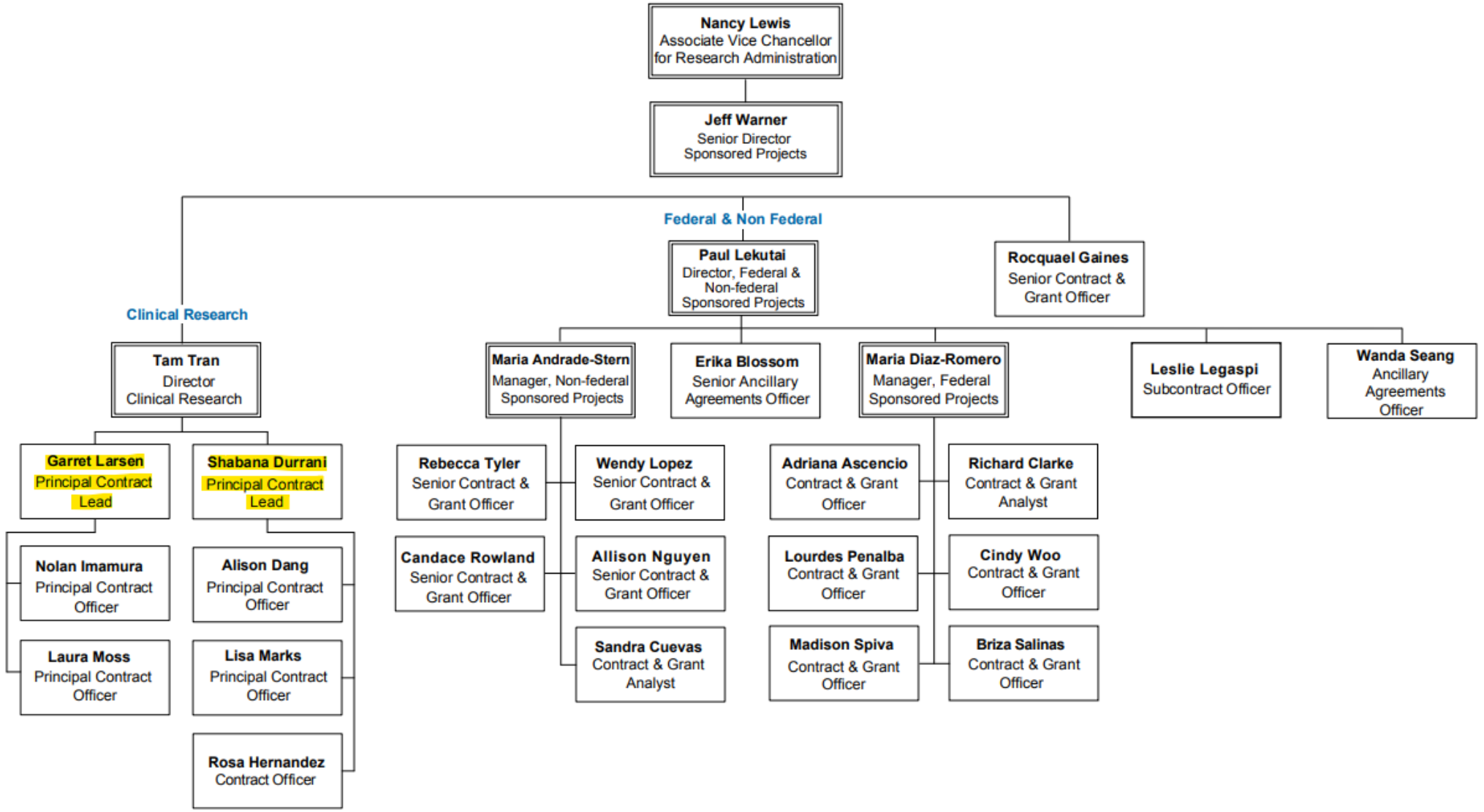
Shabana Durrani, Principal Contract Lead

- Responsible for leading the officers managing our Clinical Trial Agreements

Garrett Larsen, Principal Contract Lead

- Responsible for leading the officers managing our Clinical Research Agreements (e.g., data and biospecimen collection studies, registries), and data use agreements.

Industry Clinical Research Contracting



Revised NIH Grants Policy Statement (Rev. March 2026) for Fiscal Year 2026

UC Irvine

NIH March 2026 GPS

Section 2.3.7.13 – Appropriate Use of Artificial Intelligence (AI) (NEW)

- NIH will not consider applications substantially developed by AI to be original ideas of the applicant
- AI use may constitute plagiarism or other forms of research misconduct

Section 2.3.7.12 – NIH Application Submission Limits (NEW)

- Effective with applications submitted for the September 25, 2025 due date
- PIs limited to six new, renewal, resubmission, or revision applications per calendar year across all council rounds
- Exceptions: Training grants, R25 research education grants, and R13 conference grants

NIH March 2026 GPS

Removal of $500K Prior Approval Requirement

- NIH has removed the requirement for prior approval on unsolicited proposals of $500,000 or more in direct costs
- Consistent with NOT-OD-26-019

Section 7.9.1 – Closeout Costs

- Administrative costs specifically associated with closeout activities of an award are now allowable without NIH prior approval

Section 4.1.13 – Human Biospecimens Security Measures (NEW)

- NIH recipients must comply with the NIH Policy on Enhancing Security Measures for Human Biospecimens
- Recipients are generally prohibited from distributing covered human biospecimens of U.S. persons to institutions or parties in countries of concern, with limited exceptions
- Applies to NIH-funded research involving human clinical and research biospecimens from U.S. persons, regardless of identifiability

Section 8.8 – Alignment with Program Goals and Agency Priorities (NEW)

- NIH may terminate awards, to the extent authorized by law, if an award no longer effectuates program goals or agency priorities
- These terminations are not considered noncompliance actions and are not appealable under Uniform Guidance or the PHS Grant Appeals Procedure
- By accepting an NIH award, recipients agree continued funding is contingent on: availability of appropriated funds, satisfactory performance, compliance with Terms and Conditions, and ongoing alignment with program goals and agency priorities

NIH Guide Notices

UC Irvine

NOT-OD-26-062 - Domestic Subawards

New Requirement – Effective June 1, 2026

- All prime recipients **must obtain NIH prior approval** when **adding a new domestic subaward** post-award, if the **arrangement was not part of the original peer-reviewed and approved application**
- Intended to ensure NIH can monitor prime recipients and enforce subaward monitoring and reporting requirements

How to Submit a Request

- Submit via the eRA Commons Prior Approval Module using the "Other Request" type

Common Rule Definition of "Intervention"

Aligning NIH Policy with 45 CFR 46, Subpart A - NOT-OD-26-063

Background

- In 2014, NIH revised its clinical trial definition (NOT-OD-15-015) to improve transparency, accountability, and data precision
- NIH defined an intervention as: "A manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints"

Common Rule Definition of "Intervention"

Aligning NIH Policy with 45 CFR 46, Subpart A - NOT-OD-26-063

2018 Common Rule Definition (45 CFR 46, Subpart A) - An intervention includes:

- Physical procedures by which information or biospecimens are gathered (e.g., venipuncture)
- Manipulations of the subject or the subject's environment performed for research purposes

Common Rule Definition of "Intervention"

Aligning NIH Policy with 45 CFR 46, Subpart A - NOT-OD-26-063

NIH Policy Update

- NIH is officially adopting the Common Rule (45 CFR 46) definition of "intervention"
- **Purpose:** Ensure consistency and harmonize implementation across federal agencies
- NIH websites and forms will be updated to reflect this change

Updates to NIH Data Management and Sharing (DMS)

Updates to NIH Data Management and Sharing (DMS) Plan Elements Notice NOT-OD-26-046

What's Changing?

- NIH is streamlining DMS Plan requirements to reduce applicant burden and clarify common areas of confusion.
- The updated format is required for applications with due dates on or after May 25, 2026.

Updates to NIH Data Management and Sharing (DMS)

Updates to NIH Data Management and Sharing (DMS) Plan Elements Notice NOT-OD-26-046

New Simplified DMS Plan Elements:

- Confirm maximum appropriate sharing of scientific data (Yes/No)
- Confirm timely sharing by publication or end of performance period (Yes/No)
- Confirm data availability meets repository/journal policy minimums (Yes/No)
- If any "No" answers or limitations exist, provide justification (300 words max)
- Confirm protections for human research participant data, including access controls (Yes/No)
- List key expected data types, species/modality, and anticipated repositories (100 words max, table format)
- For studies under the NIH Genomic Data Sharing (GDS) Policy, confirm compliance with large-scale human genomic data sharing timelines and Institutional Certification expectations (Yes/No/Not Applicable)

Updates to NIH Data Management and Sharing (DMS)

Updates to NIH Data Management and Sharing (DMS) Plan Elements Notice NOT-OD-26-046

Key Takeaways:

- Plans should align with FAIR data principles (Findable, Accessible, Interoperable, Reusable)
- NIH reviewed 1,100+ DMS Plans since 2023 — many were too long with extraneous detail
- New format page will be required; draft currently available for review
- Questions? Contact sharing@nih.gov

Salary Limitation for Agreements FY 2026

NOT-OD-26-038

Effective **January 1, 2026**, the NIH salary limitation for **Executive Level II** is **$228,000.**

Implementation of the Commons Forms

UC Irvine

Implementation Timeline & Compliance

Phased Enforcement Approach for the Common Forms - NOT-OD-26-033

⚠️ **Leniency Period: January 25 – May 2026**

- Due to recent technical challenges with SciENcv and eRA systems:
- Applications without Common Forms will receive a warning
- Applications will NOT be withdrawn
- Time to prepare and adapt to new requirements

Implementation Timeline & Compliance

Phased Enforcement Approach for the Common Forms - NOT-OD-26-033

🔒 Full Enforcement: After May 2026

- NIH will issue a **Guide Notice** announcing exact enforcement date
- Non-compliant applications will receive **errors**
- Applications may be **withdrawn** for non-compliance

NIH Collaborative International Research Project

UC Irvine

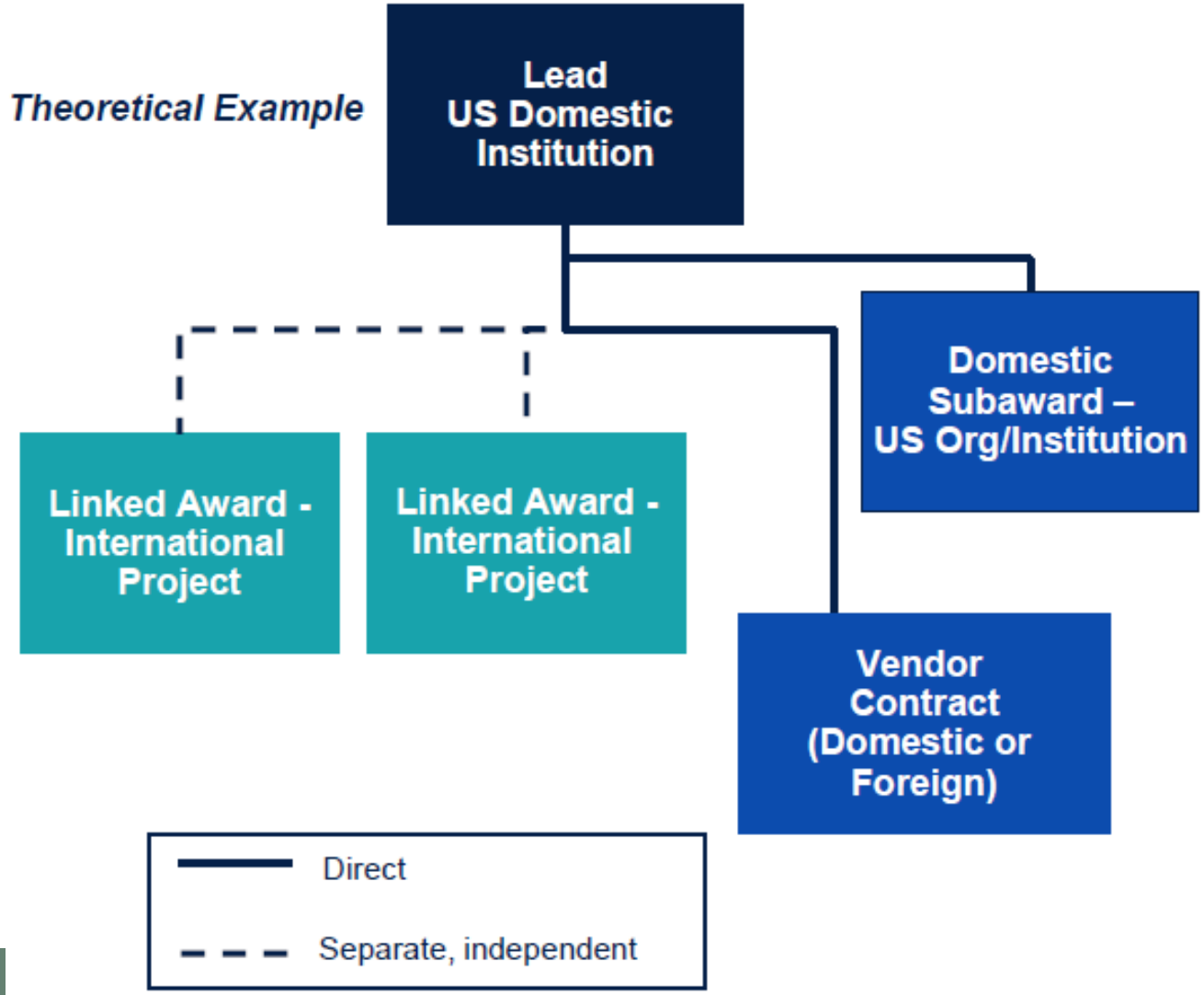
Overview - New PF5 International Collaborations

January 2026: Fundamental Policy Shift

- Policy: NOT-OD-25-104 & NOT-OD-25-155 eliminate subawards to international entities
- NOFO: PA-26-002 (NIH Collaborative International Research Project - PF5)
- **Key Change:** International collaborators now funded through International Project Components (IPCs), not subawards.

Overview - New PF5 International Collaborations

The New PF5 Mechanism



IPC Components & Mandatory Justifications

The New PF5 Mechanism

1. Will active awards with active foreign subawards be forced to shift to the PF5 mechanism?

- **TBD**

2. Will current NOAs with foreign Type 3 supplements be converted to PF5 mechanism?

- **TBD**

3. Will grant applications reviewed in the last year with fundable scores that included foreign subs continue with type 3 supplements or be converted to PF5s?

- **TBD**

IPC Components & Mandatory Justifications

Required IPC Documentation

Each International Project Component must include:

- Research Strategy
- Complete budget with detailed scope of work
- Facilities & Other Resources description
- Biosketches for all non-U.S. key personnel
- Performance site details
- All required attachments

IPC Components & Mandatory Justifications

Mandatory Justification Documents

ForeignJustification_Overall.pdf (Overall component)

- Lists ALL international components (monetary and non-monetary)
- Explains why work must occur abroad
- Describes unique resources the international environment provides

ForeignJustification_[site].pdf (One per IPC)

- Specific scientific, population, environmental, or resource advantages unique to that international site

IPC Components & Mandatory Justifications

Mandatory Justification Documents

"Research Project" Component

- Upload **ForeignJustification_ResProj1.pdf** – Required only if a domestic organization is conducting study activities outside of the U.S.
- **Note:** It is unclear whether this applies to site visit travel.

Compliance & Budget Requirements

International Organization Registration Requirements

Each international organization must complete before award issuance:

- ✓ SAM.gov registration
- ✓ NCAGE code
- ✓ UEI (can obtain via SAM.gov "Get a Unique Entity ID Only" option)
- ✓ eRA Commons account
- ✓ Grants.gov registration

Temporary placeholder UEI permitted if registration in progress

Compliance & Budget Requirements

Required Letter of Support

International AOR must acknowledge:

- Will become PD/PI of separate RF2 award
- Understands all registration requirements

IPC Budget Rules:

- International organizations receive 8% indirect costs
- UC Irvine cannot claim first $25k indirect costs (no subawards allowed)
- IPCs may not include subawards to other international organizations
- May include domestic consortia only
- Must align with scope and include salaries, equipment, compliance costs

Review Criteria & Post-Award Management

NIH Review Criteria for International Components

Reviewers will assess:

- Special opportunities not available in the U.S. or that augment U.S. resources
- Unique populations, environments, or talents essential for the science
- Administrative capability to manage an NIH award as independent RF2 recipient

Disaggregated Awards Structure (if funded):

- Separate linked awards issued:
- PF5 (domestic – UC Irvine)
- RF2 (each international organization - individual awards)

Review Criteria & Post-Award Management

Post-Award Reporting Requirements

- Each international organization becomes **direct NIH grantee**
- Each international org **submits own RPPR and financial reports**
- Domestic AOR must submit **attestation of coordination and oversight** for all linked international awards
  - Domestic AOR is "**certifying that the progress of the International Project has been satisfactory** to continue to receive funding."

Indirect Costs

UC Irvine

Federal Agency Indirect Cost Rate Caps for IHEs

Overview

National Institute of Health	Department of Energy	National Science Foundation	Department of Defense
[NOT-OD-25-068](#) (Feb. 7,2025) NOT-OD-25-068: Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates	Policy Flash of April 11, 2025 [PF 2025-22 Adjusting Department of Energy Grant Policy for Institutions of Higher Education (IHE)](#) | Department of Energy	Policy Notice of May 2, 2025 Policy Notice: [Implementation of Standard 15% Indirect Cost Rate](#) | NSF – National Science Foundation	Memo of June 12, 2025 DoD [Implementation of SECDEF Indirect Cost Cap Memo](#)
For IHEs: 15 percent cap, no identified base	For IHEs: 15 percent cap, no identified base	For IHEs: 15 percent over MTDC cap	For IHEs: 15 percent, no identified base.
Implementation halted by the courts.			

General Reminders & Updates

UC Irvine

A Friendly Reminder About Project Timelines

Sponsored Projects Recommendations

- We strongly encourage following the timeline and spending plan included in the approved proposal.

- Completing project activities and spending funds as originally proposed helps ensure successful project outcomes.

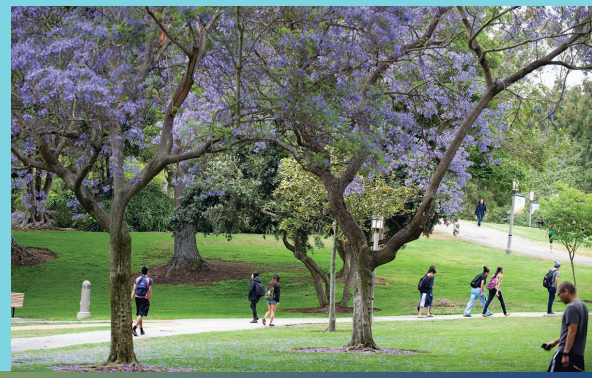
UC Irvine

A Friendly Reminder About Project Timelines

Why We're Mentioning This

- The federal funding landscape has become increasingly dynamic and less predictable over the past year.

- Practices that have been routine in the past—such as requesting multiple extensions or adjusting timelines—may not be as straightforward moving forward.



Technical Reporting

Are your reports submitted?

For federal awards, Technical Reports are required **annually and at close out**.

The Principal Investigator (PI) should also ensure that **any other agency required deliverables are submitted**.

Technical Reporting

Are your reports submitted?

Potential Institutional Risks if NOT Submitted as Required Final Technical Report and Deliverables

- Listing the institution on SAM.gov's non-compliance list, which is monitored by all federal agencies
- Withholding or delaying new and pending awards across the institution
- Suspending proposal submission privileges for individual PIs or departments
- Damaging the university's reputation and relationship with federal sponsors
- Creating barriers for other UCI researchers seeking funding from the same agencies

Technical Reporting

Submit all technical reports and deliverables no later than the agency deadline to ensure compliance, including any final technical reports due within 90 days after the project end date.

If you have questions or need assistance, please contact your Contracts and Grants Officer (https://research.uci.edu/about-or/contact/staff-by-dept-assignment/).

Please reach out if you have any questions.

warnerj@uci.edu

UC Irvine

We want to hear from you!

Provide topics and ideas and give us feedback for future QRAM by filling out this form!

See you next time!

August 19, 2026

December 9, 2026

10:00-11:30AM

UNIVERSITY OF CALIFORNIA • IRVINE