Quarterly Research Administration Meeting

March 22, 2023

Agenda

- Welcome
  - Research Security and Integrity Compliance
  - C&G Accounting Updates
  - Research Administrators United (RAU)
  - Award Setup Process
  - Human Research Protections (HRP) Updates
  - Clinical Trials Contracting Team
  - DocuSign 700U
- Q&A and Closing

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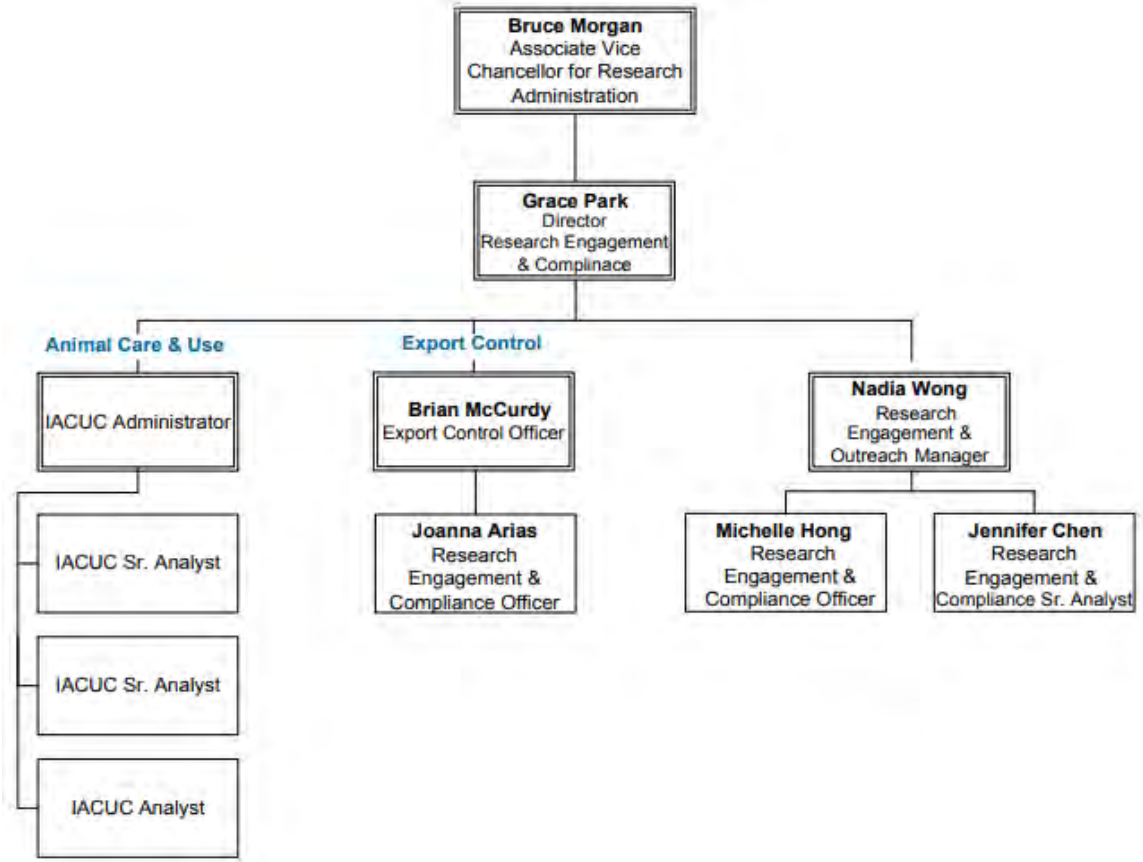
Research Engagement & Compliance Staff Update

- Brian McCurdy

Export Control Officer



RESEARCH SECURITY & INTEGRITY COMPLIANCE

BRUCE MORGAN - ASSOCIATE VICE CHANCELLOR FOR RESEARCH ADMINISTRATION
GRACE PARK - DIRECTOR, RESEARCH ENGAGEMENT & COMPLIANCE

UCI Office of Research

RESEARCH SECURITY & INTEGRITY COMPLIANCE (AKA UNDUE FOREIGN INFLUENCE)

"Undue Foreign Influence" is term used by the federal government to label its concerns about foreign governments and entities' influence in academia that appear to, or does, negatively impact the United States' economic competitiveness and national security.

UCI uses the term **Research Security and Integrity Compliance** to encompass the federal governments concerns and UCI's programs, safeguards, and procedures to address them.

Ensuring compliance with federal requirements necessitates an awareness and understanding of the government's concerns, as well as full transparency

UCI Office of Research

FEDERAL GOVERNMENT'S MAIN CONCERNS

1. Failure to fully disclose substantial foreign resources, such as:
   i. overlapping or duplicative research support from foreign entities,
   ii. foreign talents program participation,
   iii. foreign employment arrangements and time commitments, and
   iv. significant foreign financial conflicts of interest.
2. Misappropriation of **intellectual property** – For example, diverting proprietary or pre-publication information contained in grant applications or produced by US-supported research to unauthorized parties.
3. Non-compliance with US export control laws and regulations, and interactions/transactions with individuals, entities, and countries on US restricted parties and sanctions lists.

BRIEF HISTORY

- **Bi-partisan concern in Congress since at least 2015 – initially focused on intellectual property theft**
- August 2018 – Dear Colleague Letter from NIH Director Francis Collins
- January 2021 – Joint Committee on the Research Environment (JCORE) Recommended Practices for Strengthening the Security and Integrity of America's Science and Technology Research Enterprise and NSPM 33
- July 2021 – NIH Deputy Director for Extramural Research, Michael Lauer issues a Summary of Findings from 2016 – 2021
- September 2021 – DARPA issues its Risk Based Measures for Assessing UFI
- October 2021 – GAO published "Federal Research: Agency Actions Needed to Address Foreign Influence"
- December 2021 – DARPA issues revised Risk Based Measures for Assessing UFI

BRIEF HISTORY

- January 2022 – National Science and Technology Council issued its Guidance for Implementing NSPM-33
- January 25, 2022 – Changes to NIH Other Support and Biographical Sketch requirements (other agencies are developing their own rule changes)
- August 2022 – Congress passes CHIPS (Creating Helpful Incentives to Produce Semiconductors) & Science Act, which promulgates certain research security requirements
- March 2023 – Office of Science and Technology Policy issues Draft Research Security Programs Standard Requirement
  - Foreign travel security
  - Research security training
  - Cybersecurity
  - Export control training

INTERNATIONAL COMMUNITY

"UCI embraces and promotes international collaborations because we are dedicated to academic freedom and an open, inclusive academic environment. We strongly believe that global collaborations accelerate research, education and mutual understanding." – Chancellor Gillman's Dear Colleague Letter on UCI's Commitment to International Collaborations
(October 28, 2021)

FEDERAL GOVERNMENT'S FOCUS - DISCLOSURE

The federal government's clarifications, updates, and investigations related to Research Security and Integrity Compliance primarily arise from problems with researchers' disclosures (incomplete, inaccurate, inconsistent, etc.).

The federal government expects researchers to comply with the multiple disclosure requirements to promote transparency and to enable well-informed funding decisions.

The federal government's use of these disclosures (as well as, public and third-party information) to conduct comprehensive reviews of researchers' relationships and in some cases raise concerns about inconsistencies to the researchers' institutions.

GENERAL DISCLOSURE REQUIREMENTS

Who Needs to Disclose	What Needs to be Disclosed	When to Disclose	Who to Disclose to	Contact/Resources
UCI Employees	Intellectual Property - Record of Invention	Submitted after invention's discovery	UCI Beall Applied Innovation Research Translation Group	Research Translation Group at cove@uci.edu
UCI Faculty	Conflict of Commitment: outside professional activities in UC OATS	Annually based on the fiscal calendar; Prior Approval for Category I Activities, involving students, or exceeding limit	UCI Academic Personnel	Academic Personnel Directory
Researchers (varies based on applicable Conflict of Interest policy(ies)- see COI Disclosure Requirements	• Conflict of Interest: personal outside financial interests • Public Health Service/National Science Foundation: KR COI Annual Disclosure • Other policies have different disclosure procedures	With certain research project-based transactions (such as proposal, award, continuing award, etc.)	UCI Conflict of Interest	Conflict of Interest (Office of Research) at coioc@research.uci.edu
Researchers (varies by federal agency)	Biographical sketches: positions, affiliations, etc.	In federal grant/contract applications	Federal Agency	Sponsored Projects Departmental Assignment
Researchers (varies by federal agency)	Other Support/Current & Pending Support: research related resources, collaborations, etc.-see Research Grant Applications Current or Pending Research Support	At just-in-time/with application and updated with federal project's annual progress reports	Federal Agency	Sponsored Projects Departmental Assignment

UCI'S RESPONSE AND ACTIONS

- Undue Foreign Influence Work Group led by the Office of Research
- Developing local resources and promoting awareness – OR Website
- OR is participating in systemwide efforts related to Research Security and Integrity Compliance and participates in national advocacy efforts (e.g., AAU, APLU, COGR, etc.)
- OR is addressing concerns of consistent disclosures by adding questions to KR proposal regarding foreign employment, consulting or appointments, foreign government talent recruitment programs and foreign government research funding

QUESTIONS?

Bruce Morgan

Associate Vice Chancellor for Research Administration

bruce.morgan@uci.edu

Grace Park

Director, Research Engagement & Compliance

parkgj@uci.edu

Agenda

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  - Research Security and Integrity Compliance
  - ***C&G Accounting Updates***
  - Research Administrators United (RAU)
  - Award Setup Process
  - Human Research Protections (HRP) Updates
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  - DocuSign 700U
- Q&A and Closing

Contracts & Grants Accounting

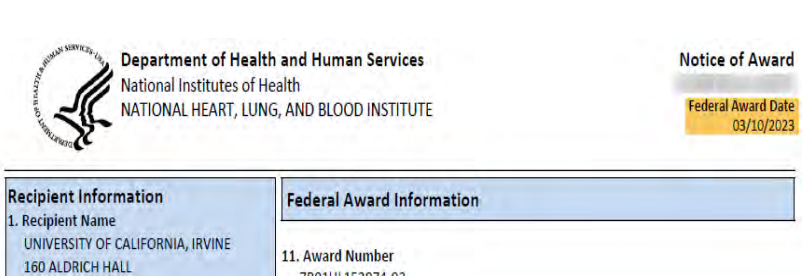
Beata Najman

Director, Extramural Funds Accounting

Agenda

- C&G Accounting general updates
  - Org Chart changes and staffing update
  - Clinical trials managed by two C&G Accountants
- Additional payroll certification requirement for November and December 2022 (due by June 30, 2023)
- Award Execution Date – new field in KFS
- NSF Award(s) with Canceling Funds
- C&G Training in April

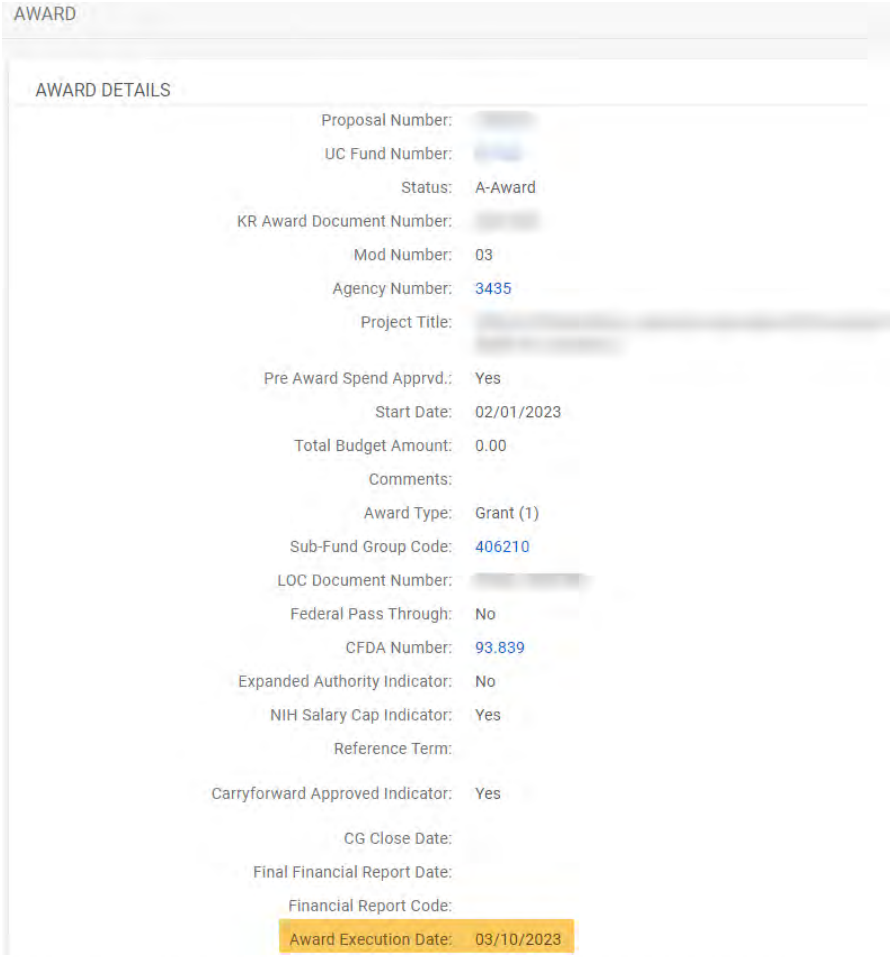
Award Execution Date



Department of Health and Human Services
National Institutes of Health
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Notice of Award
[redacted]
Federal Award Date
03/10/2023

Recipient Information	Federal Award Information
1. Recipient Name UNIVERSITY OF CALIFORNIA, IRVINE 160 ALDRICH HALL	11. Award Number [redacted]



AWARD

AWARD DETAILS

Proposal Number:	[redacted]
UC Fund Number:	[redacted]
Status:	A-Award
KR Award Document Number:	[redacted]
Mod Number:	03
Agency Number:	3435
Project Title:	[redacted]
Pre Award Spend Apprvd.:	Yes
Start Date:	02/01/2023
Total Budget Amount:	0.00
Comments:	
Award Type:	Grant (1)
Sub-Fund Group Code:	406210
LOC Document Number:	[redacted]
Federal Pass Through:	No
CFDA Number:	93.839
Expanded Authority Indicator:	No
NIH Salary Cap Indicator:	Yes
Reference Term:	
Carryforward Approved Indicator:	Yes
CG Close Date:	
Final Financial Report Date:	
Financial Report Code:	
Award Execution Date:	03/10/2023

<u>Award Execution Date in KFS</u>

1. If a Federal award, the Award Execution Date is the same as the Federal Award Date from the NOA or FDP template.

NSF Award(s) with Canceling Funds

From: DFM Payments and Analytics Branch
Sent: Monday, March 20, 2023 1:29 PM
To: University Of California-Irvine
Subject: NSF Award(s) with Canceling Funds

Dear Awardee:
This email is to notify you that your institution has National Science Foundation (NSF) award(s) with appropriations that will be canceled by the U.S. Department of Treasury after September 30, 2023, and in accordance with 31 USC 1552(a), **thereafter shall not be available for obligation or expenditure for any purpose.**
Please note, although the official canceling date is September 30, 2023, the NSF ACM$ system will only be available to awardees for drawdown transactions until 2pm EDT on Monday, September 25, 2023, in order for NSF to financially close for the fiscal year. Your institution may incur allowable costs against funds that will cancel this fiscal year through the award end date or September 30, 2023, whichever comes first. However, you must drawdown these funds by 2pm on Monday, September 25, 2023, otherwise those funds will cancel and be returned to the U.S. Treasury.
As of the date of this notification, the following awards have unliquidated funds that will cancel at the end of this fiscal year and no further drawdowns are allowed after 2pm EDT, Monday, September 25, 2023

C&G Training

COURSE #1 **(CGS 1) Introduction to Fund Management**
Tuesday, Apr. 4, 10:30 a.m. – 12 p.m.

COURSE #2 **(CGS 2) Direct vs. F&A**
Thursday, Apr. 6, 10:30 a.m. – 12 p.m.

COURSE #6 **(CGS 6) Ledger Reading and Award Closeout**
Tuesday, Apr. 11, 10:15 a.m. – 12 p.m.

Available in UCLC as an eCourse

COURSE #3 **(CGS 3) General Error Correction (GEC)/Cost Transfers**
COURSE #4 **(CGS 4) Payroll Certification**
COURSE #5 **(CGS 5) Cost Sharing**

Questions?

Beata Najman

Director, Extramural Funds Accounting

bnajman@uci.edu

Agenda

- Welcome
  - Research Security and Integrity Compliance
  - C&G Accounting Updates
  - ***Research Administrators United (RAU)***
  - Award Setup Process
  - Consent addendum for the 2023 DMS
  - CT.gov Compliance
  - Clinical Trials Contracting Team
  - DocuSign 700U
- Q&A and Closing

Goals

- Build relationships between DRAs in different departments and strengthen DRAs relationship with SPA
- Increase awareness of research administrator resources available on and off campus (e.g., NCURA, RESADM listserv)
- Work to fill the training gap. Ask questions, get answers, attend sessions and workshops, get trained
- Create an organization to represent research administrators on campus

To sign up for the listserv send an email to:

DRAgroup@maillists.uci.edu

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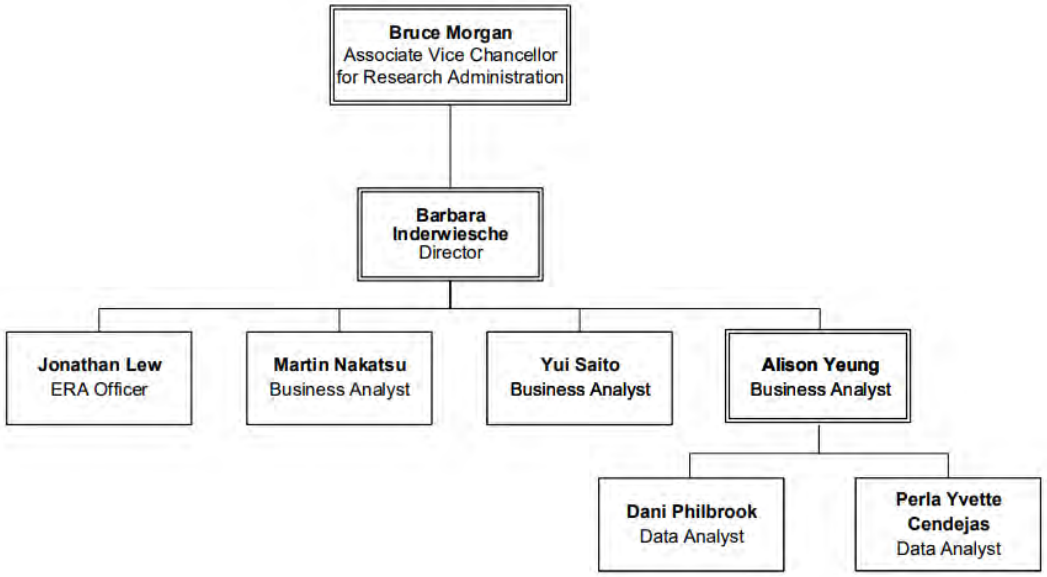
Award Setup Process

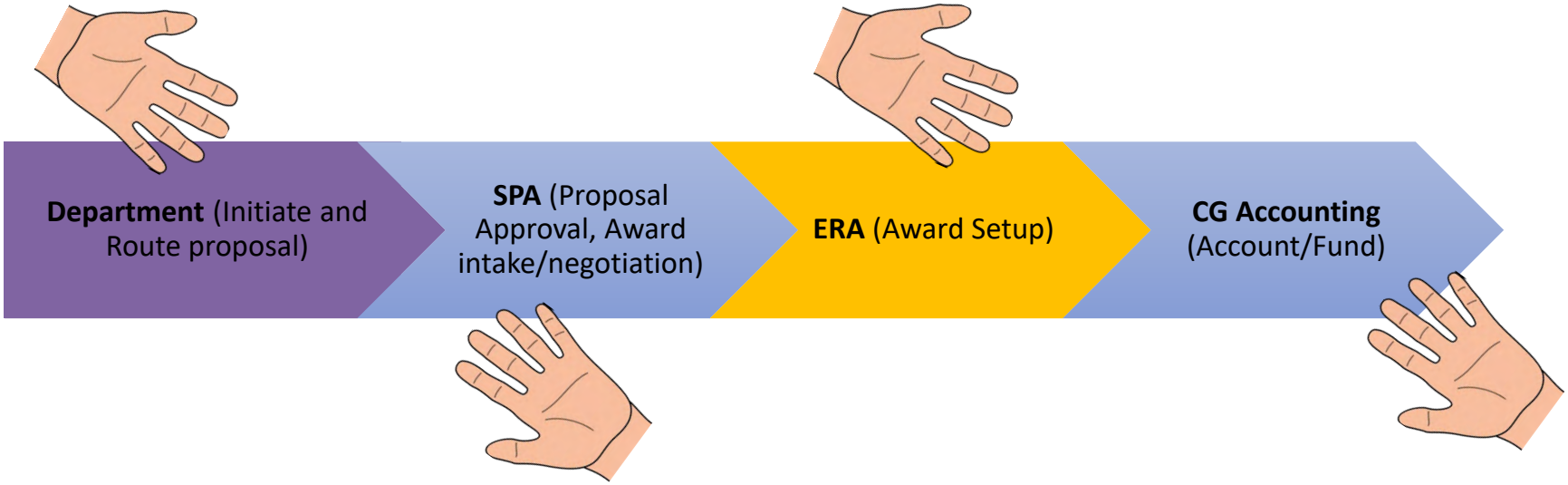
Alison Yeung and the ERA Data Team

ERA Data Team

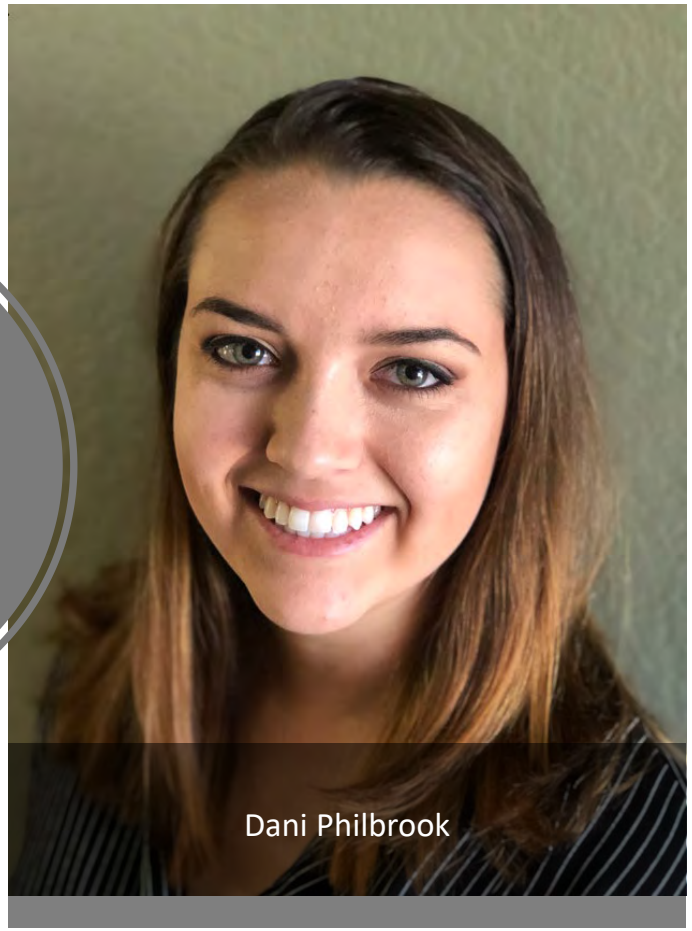
- Award processing and data management
- Award Transaction Summary (ATS) and ATS/CG Emails
- Non-funded Agreements processing
- Outgoing subawards data and FFATA
- Proposal Denials processing



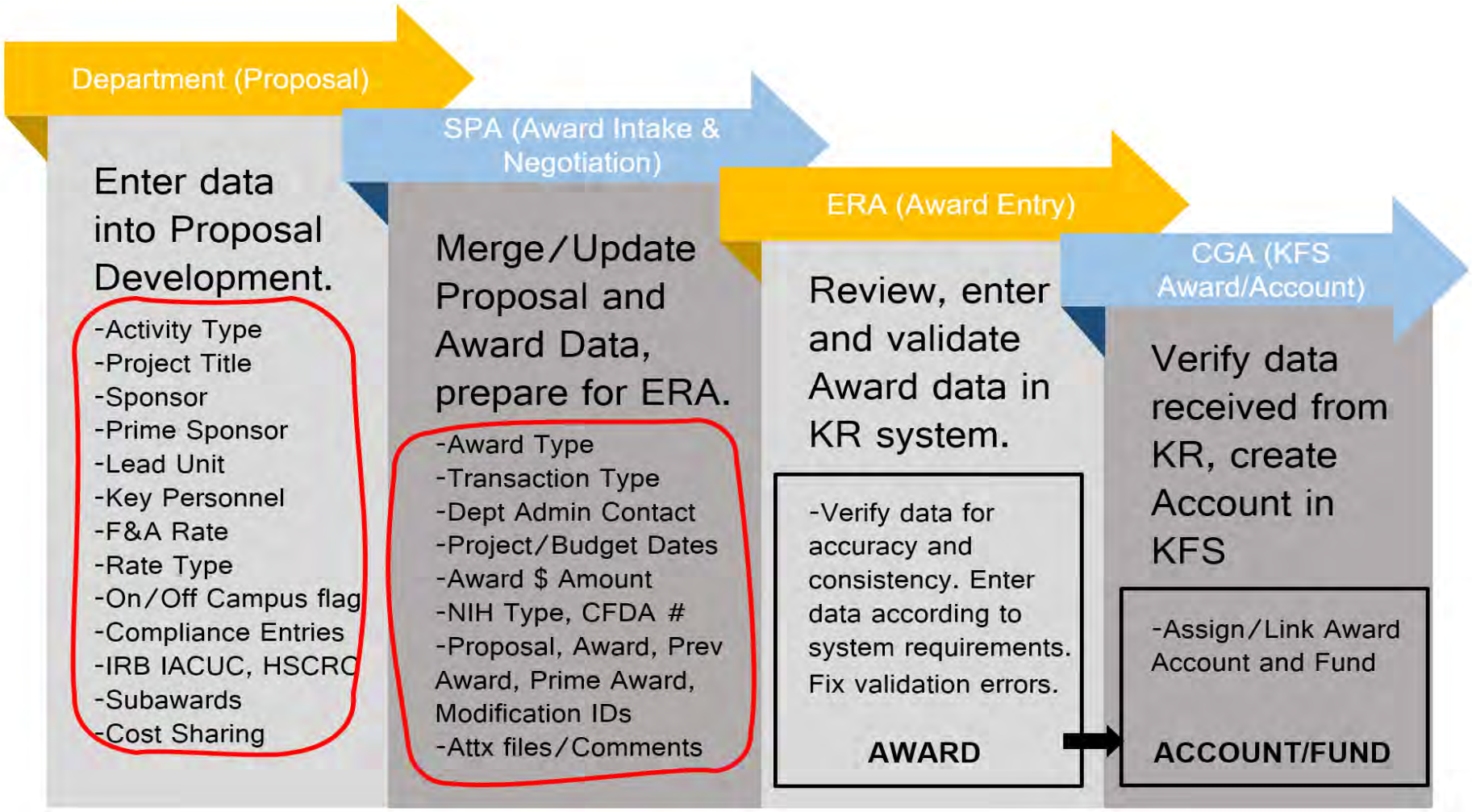
Who touches the data?



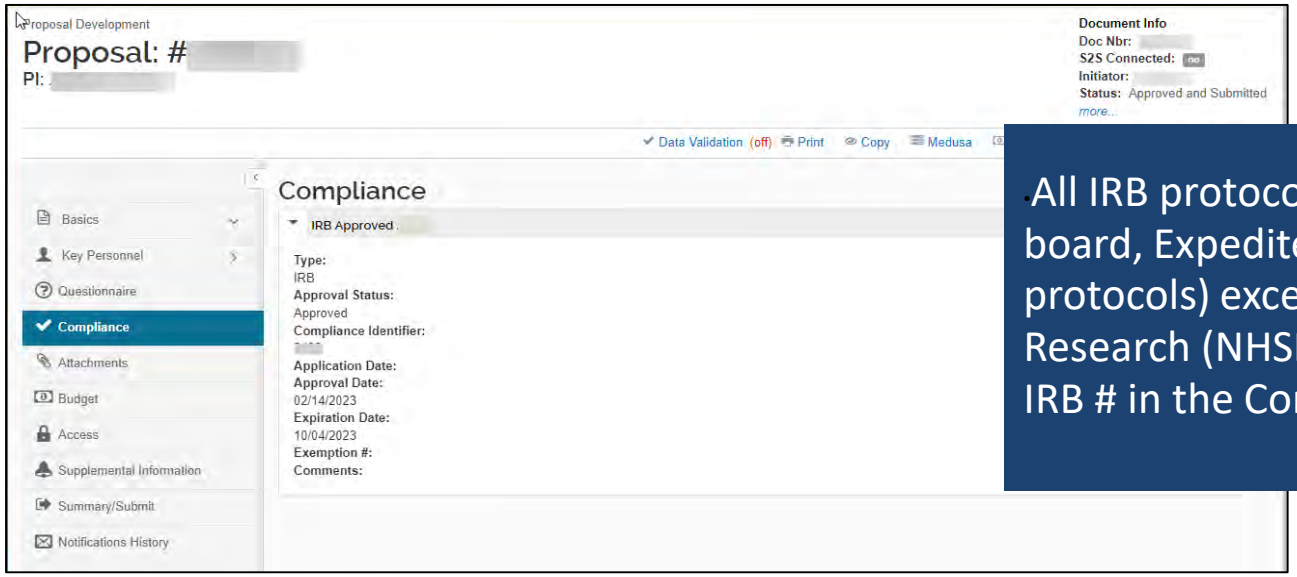
Meet the ERA Data Analysts



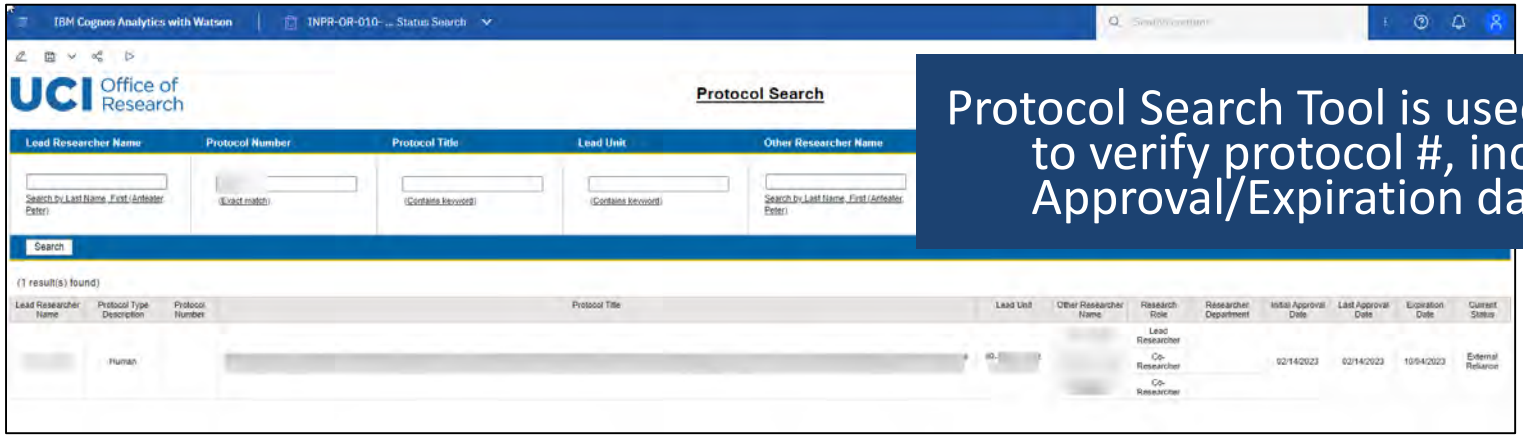
The flow of shared data: Proposal to Award to Account



Compliance Entries in Proposal Development



All IRB protocols should be entered (Full board, Expedited, Exempt, Self-Exempt protocols) except Non-Human Subjects Research (NHSR). For Reliance, enter UCI IRB # in the Compliance Identifier.



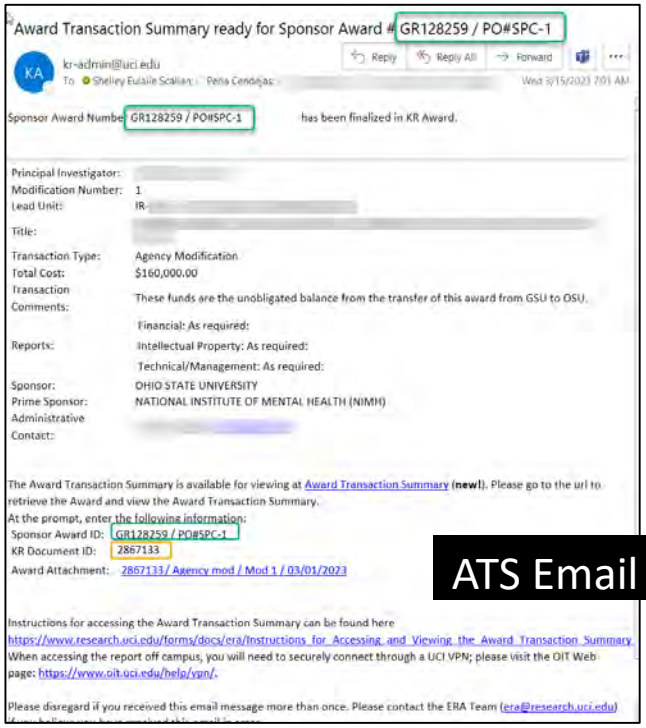
Protocol Search Tool is used by ERA to verify protocol #, including Approval/Expiration dates.

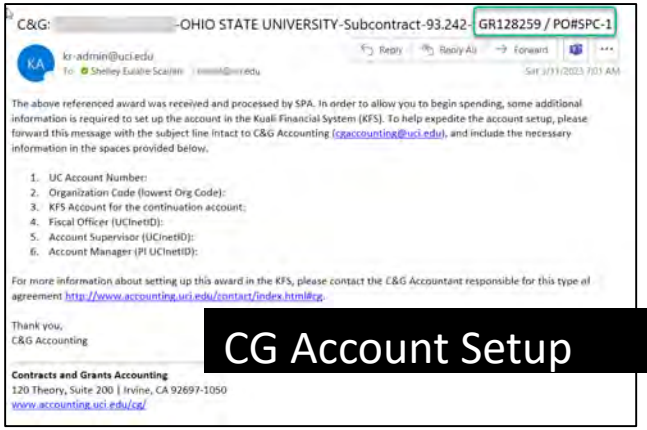
Award Emails From kr-admin@uci.edu

	ATS Email	CG Account Setup Email
Sent for NEW and RENEWAL transactions		X
Sent for ALL transactions	X	
References KR Doc #	X	
References Sponsor Award #	X	X
Sent to Dept Admin Contact listed in the award *	X	X
Sent to the assigned SPA Officer	X	X
Action required?		**X ***

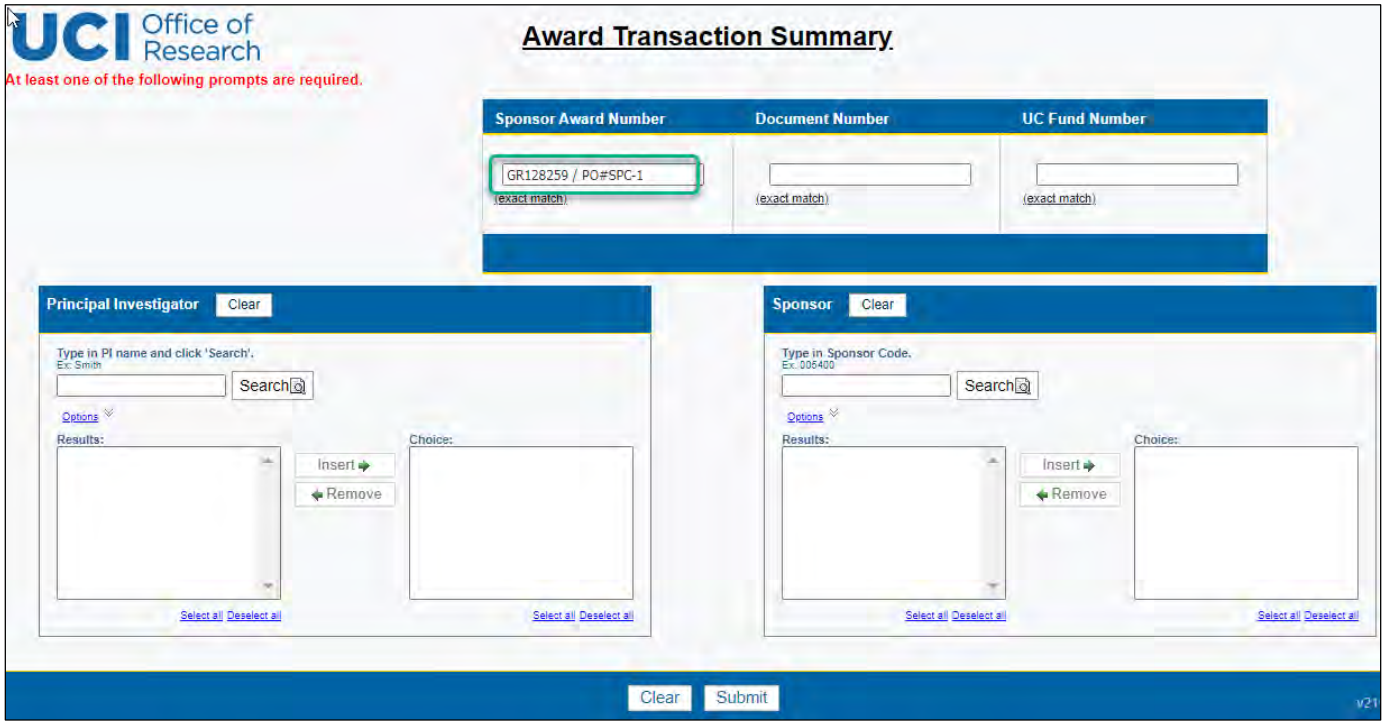
- Notify your SPA Officer or ERA of any changes to Dept Admin contact

*Be sure to send Account setup info to cgaccounting@uci.edu (not ERA)



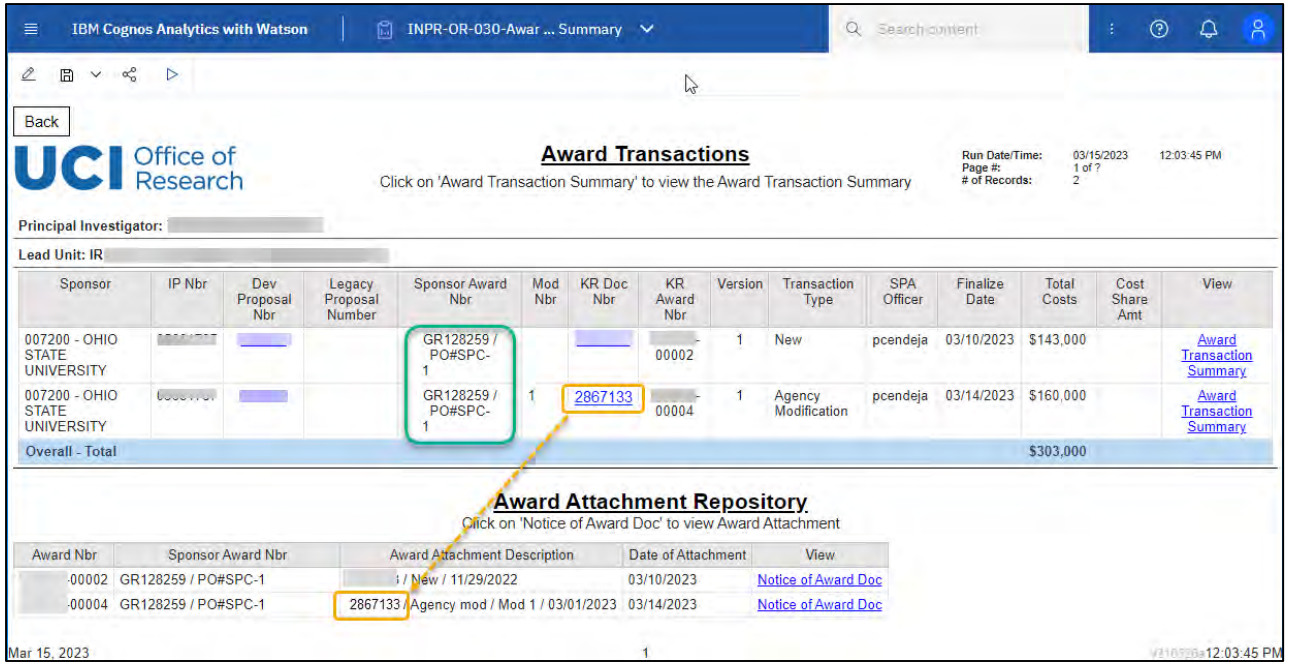


ATS Search



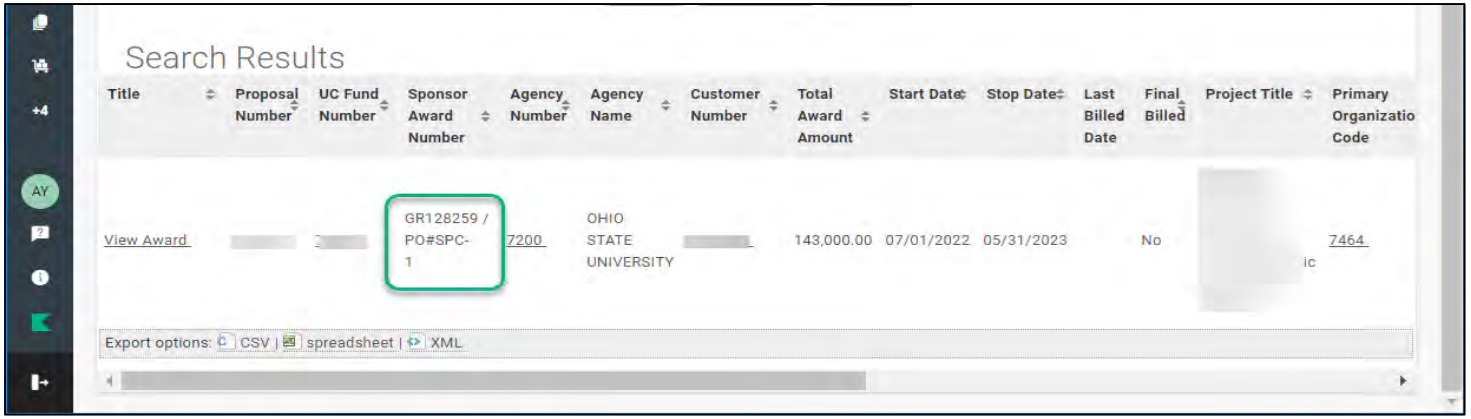
- Can be accessed from ATS email or from ZotPortal > Faculty/Staff > Research
- Enter Document Number to view **single** transaction only
- Enter Sponsor Award # to view **all transactions that share Award #**
- Enter Fund # to view **all transactions that share Fund #**

Sponsor Award # is shared by KFS and KR/ATS



Sponsor	IP Nbr	Dev Proposal Nbr	Legacy Proposal Number	Sponsor Award Nbr	Mod Nbr	KR Doc Nbr	KR Award Nbr	Version	Transaction Type	SPA Officer	Finalize Date	Total Costs	Cost Share Amt	View
007200 - OHIO STATE UNIVERSITY				GR128259 / PO#SPC-1			-00002	1	New	pcendeja	03/10/2023	$143,000		Award Transaction Summary
007200 - OHIO STATE UNIVERSITY				GR128259 / PO#SPC-1	1	2867133	-00004	1	Agency Modification	pcendeja	03/14/2023	$160,000		Award Transaction Summary
Overall - Total												$303,000		

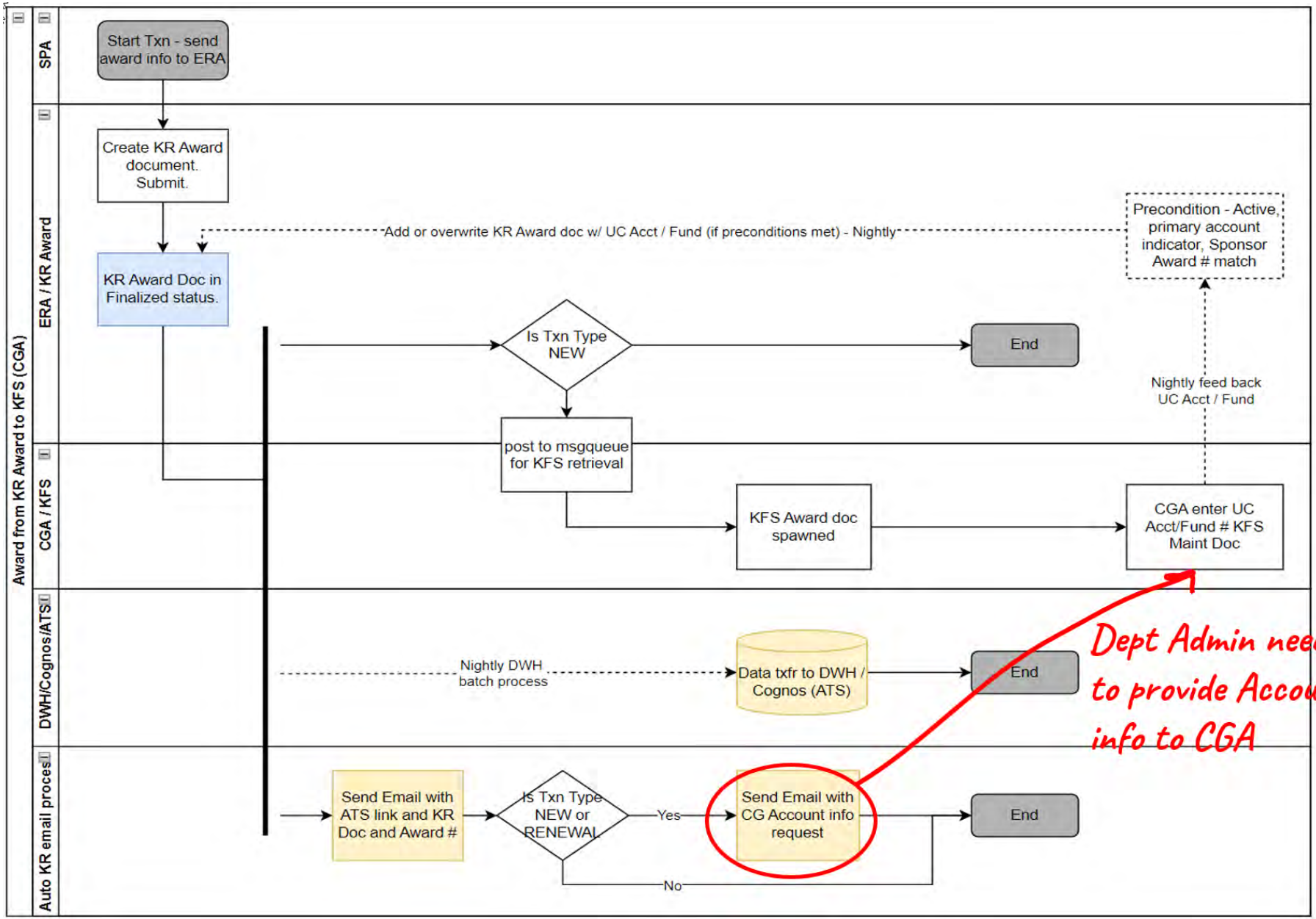
Award Nbr	Sponsor Award Nbr	Award Attachment Description	Date of Attachment	View
-00002	GR128259 / PO#SPC-1	/ New / 11/29/2022	03/10/2023	Notice of Award Doc
-00004	GR128259 / PO#SPC-1	2867133 / Agency mod / Mod 1 / 03/01/2023	03/14/2023	Notice of Award Doc



Title	Proposal Number	UC Fund Number	Sponsor Award Number	Agency Number	Agency Name	Customer Number	Total Award Amount	Start Date	Stop Date	Last Billed Date	Final Billed	Project Title	Primary Organizatio Code
View Award			GR128259 / PO#SPC-1	7200	OHIO STATE UNIVERSITY		143,000.00	07/01/2022	05/31/2023		No	ic	7464

UCI Office of Research
Research Administration

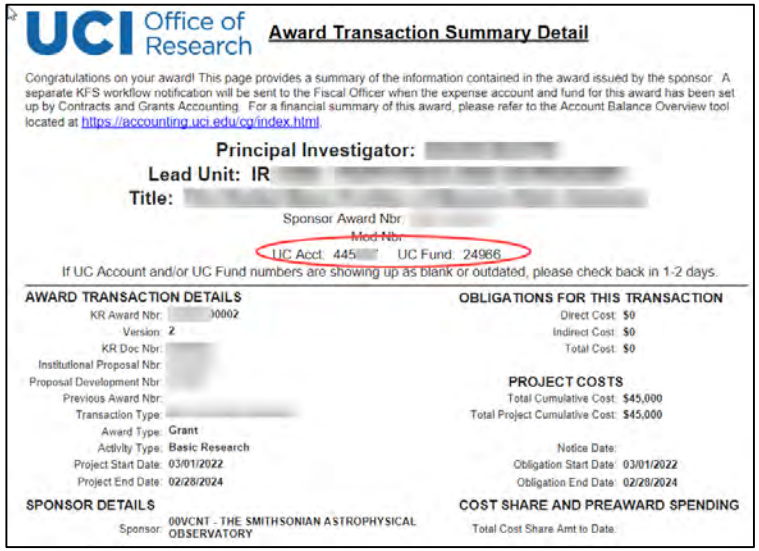
Award Workflow: KR Award to KFS and ATS



Account/Fund pullback from KFS (to KR/ATS)

ATS pulls back UC Account / Fund updates automatically after certain criteria are met:

- Sponsor Award Id matches in KR and KFS.
- Fund # has been linked to Award in KFS, is marked as Active, and there is an Account indicated as Primary Award Account.
- Occasionally, ERA will need to perform manual updates to the UC Account/Fund.



UCI Office of Research **Award Transaction Summary Detail**

Congratulations on your award! This page provides a summary of the information contained in the award issued by the sponsor. A separate KFS workflow notification will be sent to the Fiscal Officer when the expense account and fund for this award has been set up by Contracts and Grants Accounting. For a financial summary of this award, please refer to the Account Balance Overview tool located at https://accounting.uci.edu/cg/index.html.

Principal Investigator: [redacted]
Lead Unit: IR [redacted]
Title: [redacted]
Sponsor Award Nbr: [redacted]
Mod Nbr:
UC Acct: 445[redacted] UC Fund: 24986
If UC Account and/or UC Fund numbers are showing up as blank or outdated, please check back in 1-2 days.

AWARD TRANSACTION DETAILS
KR Award Nbr: [redacted]0002
Version: 2
KR Doc Nbr: [redacted]
Institutional Proposal Nbr: [redacted]
Proposal Development Nbr: [redacted]
Previous Award Nbr: [redacted]
Transaction Type: [redacted]
Award Type: Grant
Activity Type: Basic Research
Project Start Date: 03/01/2022
Project End Date: 02/28/2024

OBLIGATIONS FOR THIS TRANSACTION
Direct Cost: $0
Indirect Cost: $0
Total Cost: $0

PROJECT COSTS
Total Cumulative Cost: $45,000
Total Project Cumulative Cost: $45,000

Notice Date:
Obligation Start Date: 03/01/2022
Obligation End Date: 02/28/2024

SPONSOR DETAILS
Sponsor: 00VCNT - THE SMITHSONIAN ASTROPHYSICAL OBSERVATORY

COST SHARE AND PREAWARD SPENDING
Total Cost Share Amt to Date:

Please contact ERA if A/F is not showing up properly in ATS. However, please remember that it takes an overnight process to pull the A/F back into ATS *after* CGA updates KFS. **"If UC Account and/or UC Fund numbers are showing up as blank or outdated, please check back in 1-2 days."**

Who to contact?

- **SPA**
  - Sent award notices / NOGAs to SPA.
  - Regarding new awards or funding that need to be added to the award.
  - Award terms/conditions or
  - If you/PI obtain approval for a NCTE or other award action that must be vetted by SPA.
- **ERA** (ERADataTeam@uci.edu)
  - Questions about ATS emails, attachments, or accessing/using the ATS Search.
  - Errors on the ATS that require corrections. We will loop in SPA as necessary.
  - Issues with the award data in DWH.
- **CG Accounting**
  - Questions about KFS or Account related questions.
  - If you receive a check or award notice directly from the sponsor. CGA will loop in SPA/ERA as necessary.

See the List of Resources table on the next slide

UCI Office of Research
Research Administration

List of Resources

Resource	Purpose	Link or email
ERA Data Team ★	Award or ATS related questions	Email: ERADatateam@uci.edu
ERA General Inbox	General ERA helpdesk, Systems, login account related questions	Email: ERA@research.uci.edu
Award Transaction Summary (ATS)	Search for Award transactions by Sponsor Award # (all transactions), Fund # (all transactions that share a Fund #), or KR Doc # (single transaction)	ZotPortal (sign in) » Faculty & Staff » Research » Kuali Research Award > *Award Transaction Summary (ATS) Search*
Contracts & Grants Accountant Lookup Tool, or Contracts & Grants Accountant in KFS	Look Up Your CGA Accountant for KFS Award/Account by PI, Fund #, Sponsor Award #	https://www.accounting.uci.edu/cg/lookup-accountant.html
SPA Staff Directory	Determine who is your assigned SPA Officer (Federal, Non Federal, Industry, Industry Clinical Trial, Principal). *Send Award Notices and NOGA to this SPA Contact.	https://research.uci.edu/about-or/contact/staff-by-dept-assignment/ (UCI Office of Research webpage » About the Office of Research » Contact » Staff by Department Assignment)
Protocol Status Search (Protocol Search Tool)	Check the status of a protocol (including Approval/Expiration Dates)	ZotPortal (sign in) » Faculty & Staff » Research » Research Tools & Support » Research Protections » *Protocol Status Search*
Negotiation Queues	Check the status of an in-progress negotiation for an incoming Award or Clinical Trial.	ZotPortal (sign in) » Faculty & Staff » Research » Kuali Research Negotiations. *Negotiation Activities* (all awards except CT) or *Status of Industry Clinical Trial Negotiations* (only CTs)

Questions?

Alison Yeung

yeunga@uci.edu

OR

ERADataTeam@uci.edu

Award Setup - CGA

Beata Najman
Director, Extramural Funds Accounting

Award Setup

- Sponsored Projects Administration (SPA) notifies Contracts & Grants Accounting (CGA) of award approval, and system spawns Award Document from Kuali Research (KR) to Kuali Financial System (KFS).

- KR sends a notification to lead unit/department asking for the award setup details

- **Award setup cannot be completed in KFS unless additional information is sent to** cgaccounting@uci.edu by the lead unit/department as specified in the notification sent by KR.

UCI Office of Research

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Principal Investigator: [redacted]
Lead Unit: [redacted]
Title: [redacted]

Sponsor Award Nbr: [redacted]
Mod Nbr: 01
UC Acct: 444000 UC Fund: [redacted]
If UC Account and/or UC Fund numbers are showing up as blank or outdated, please check back in 1-2 days.

AWARD TRANSACTION DETAILS

KR Award Nbr: [redacted]
Version: 1
KR Doc Nbr: [redacted]
Institutional Proposal Nbr: [redacted]
Proposal Development Nbr: [redacted]
Previous Award Nbr:
Transaction Type: New
Award Type: Grant
Activity Type: Basic Research
Project Start Date: 03/01/2023
Project End Date: 02/29/2028

OBLIGATIONS FOR THIS TRANSACTION

Direct Cost: $267,645
Indirect Cost: $148,179
Total Cost: $415,824

PROJECT COSTS

Total Cumulative Cost: $415,824
Total Project Cumulative Cost: $415,824

Notice Date:
Obligation Start Date: 03/01/2023
Obligation End Date: 02/29/2024

SPONSOR DETAILS

Sponsor: 005013 - NATIONAL INSTITUTES OF HEALTH CENTER FOR SCIENTIFIC REVIEW
Prime Sponsor:
On/Off Campus: On-Campus
*F & A Rate: 57.0 MTDC

COST SHARE AND PREAWARD SPENDING

Total Cost Share Amt to Date:
RAS Amt:
RAS Date:
RAS Comments:

Sponsor Terms

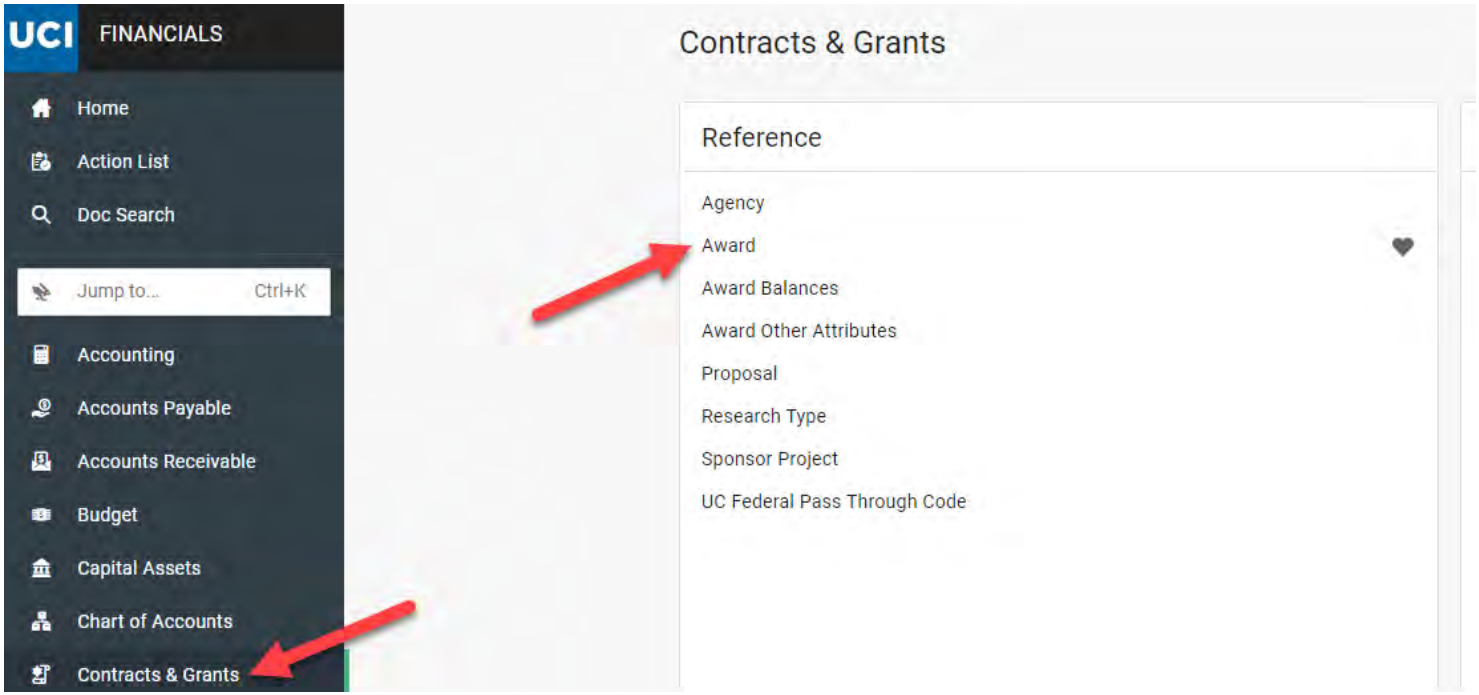
Equipment Approval Terms:	Equipment can be purchased as approved in the Award.
Invention Terms:	Standard UCI patentable IP terms and conditions.
Prior Approval Terms:	Prior approval required for change in PI, 3 month absence or 25% reduction in effort.
Property Terms:	Title to UCI
Publication Terms:	Unrestricted
Referenced Document Terms:	An Unobligated balance may be carried over into the next budget period without Grants Management Officer's prior approval SNAP

C&G Accounting (CGA) sets up an award in the Kuali Financial System (KFS) and completes the following tasks:

- Perform a detailed review of the terms and conditions
- Populate Full Accounting Unit (FAU) attributes, award billing, financial reporting, and budget periods for payroll certification and cost sharing (if applicable)
- Assign Fund Number in the Award Document
- Establish UC Control Account
- Establish Expense Account(S)
- Allocate budget

Budget ≠ Cash

Award Lookup in KFS



AWARD DETAILS

Proposal Number:	[redacted]	UC Location Code:	9
UC Fund Number:	[redacted]	Last Update Date:	03/14/2023 01:58 PM
Status:	A-Award	Transaction Type Code:	New (9)
KR Award Document Number:	[redacted]	SPA Proposal Number:	[redacted]
Mod Number:	01	Cost Share Total Amount:	
Agency Number:	5013	Agency Reporting Name:	NATIONAL INSTITUTES OF HEALTH
Project Title:	[redacted]	Sponsor Award Number:	[redacted]
Pre Award Spend Apprvd.:	Yes	Prime Award Number :	
Start Date:	11/30/2022	Stop Date:	02/29/2028
Total Budget Amount:	0.00	ICR Waiver Number:	
Comments:		Entry Date:	03/09/2023
Award Type:	Grant (1)	Purpose:	Basic Research (1)
Sub-Fund Group Code:	406210	Payment Method Code:	90 - Payment by Letter of Credit
LOC Document Number:	[redacted]	Pass Through Code:	
Federal Pass Through:	No	Pass Through Agency Name:	
CFDA Number:	93.859	RTC Indicator:	No
Expanded Authority Indicator:	No	SNAP Indicator:	Yes
NIH Salary Cap Indicator:	Yes	E-Verify:	No
Reference Term:		Other Attributes Code:	R
Carryforward Approved Indicator:	Yes	Departmental CG Certification Administrator:	[redacted]
CG Close Date:		Equipment Reporting Required:	No
Final Financial Report Date:		Final Financial Report Amount:	
Financial Report Code:		Financial Due Date:	05/31/2028
Award Execution Date:	02/27/2023	Active Indicator:	Yes

Questions?

Beata Najman

Director, Extramural Funds Accounting

bnajman@uci.edu

Stretch Break
<5 minutes>

Agenda

- Welcome
  - Research Security and Integrity Compliance
  - C&G Accounting Updates
  - Research Administrators United (RAU)
  - Award Setup Process
  - ***Human Research Protections (HRP) Updates***
  - Clinical Trials Contracting Team
  - DocuSign 700U
- Q&A and Closing

UCI Office of Research

2023 SPRING QRAM
HUMAN RESEARCH PROTECTIONS UPDATES

Anu Mathur, MS, CIP
Education and Quality Improvement Program Administrator
Interim IRB-A and hSCRO Administrator
PRS Administrator (ClinicalTrials.gov)
anuradhm@uci.edu
(949) 824-9819

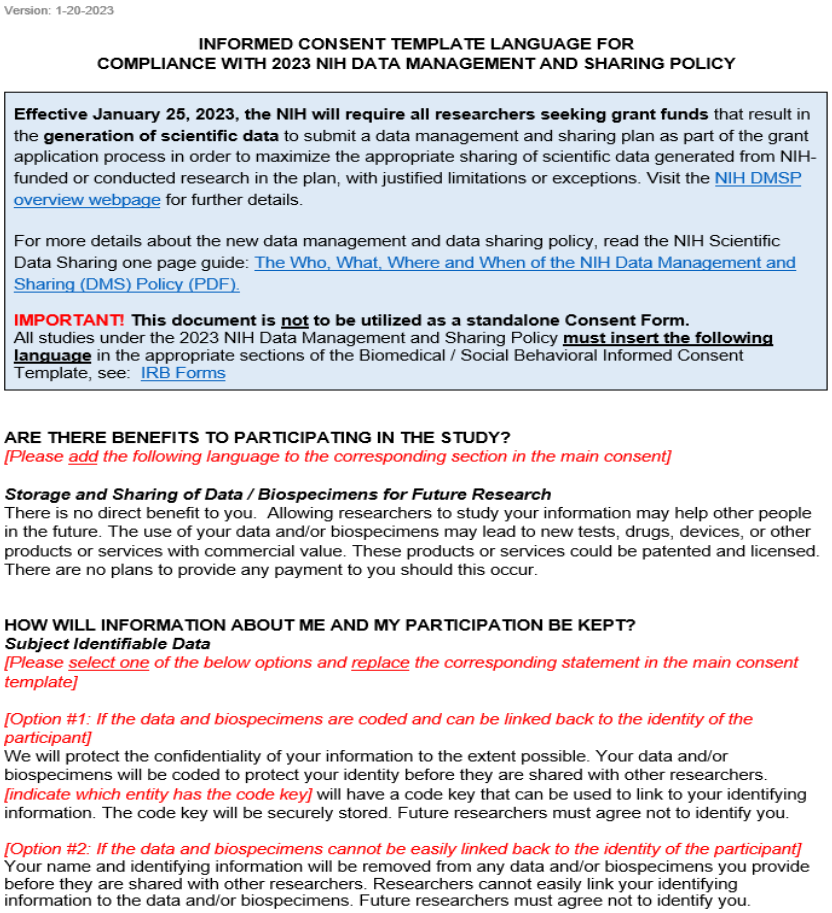
NIH's 2023 Data Management & Sharing Policy (DMSP)

Effective January 25, 2023

- Requires researchers seeking **NIH funding** to submit a plan outlining **how scientific data** from their research **will be managed and shared**.
  - Excellent tool to help determine which NIH Policies apply to your research: **https://sharing.nih.gov/other-sharing-policies/which-policies-apply-to-my-research**
  - See the **Office of Research Listserv** for more information and resources.

NIH's 2023 Data Management & Sharing Policy (DMSP)

- If NIH's 2023 DMSP is applciable to your Human Subject's Research protocol which includes participant **Consent**, please add the NEW "NIH Data Management and Sharing" Consent Template language to the main Consent Form.
- IRB Forms Page



Version: 1-20-2023

INFORMED CONSENT TEMPLATE LANGUAGE FOR COMPLIANCE WITH 2023 NIH DATA MANAGEMENT AND SHARING POLICY

Effective January 25, 2023, the NIH will require all researchers seeking grant funds that result in the **generation of scientific data** to submit a data management and sharing plan as part of the grant application process in order to maximize the appropriate sharing of scientific data generated from NIH-funded or conducted research in the plan, with justified limitations or exceptions. Visit the NIH DMSP overview webpage for further details.

For more details about the new data management and data sharing policy, read the NIH Scientific Data Sharing one page guide: The Who, What, Where and When of the NIH Data Management and Sharing (DMS) Policy (PDF).

IMPORTANT! This document is not to be utilized as a standalone Consent Form.
All studies under the 2023 NIH Data Management and Sharing Policy **must insert the following language** in the appropriate sections of the Biomedical / Social Behavioral Informed Consent Template, see: IRB Forms

ARE THERE BENEFITS TO PARTICIPATING IN THE STUDY?
[Please add the following language to the corresponding section in the main consent]

Storage and Sharing of Data / Biospecimens for Future Research
There is no direct benefit to you. Allowing researchers to study your information may help other people in the future. The use of your data and/or biospecimens may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?
Subject Identifiable Data
[Please select one of the below options and replace the corresponding statement in the main consent template]

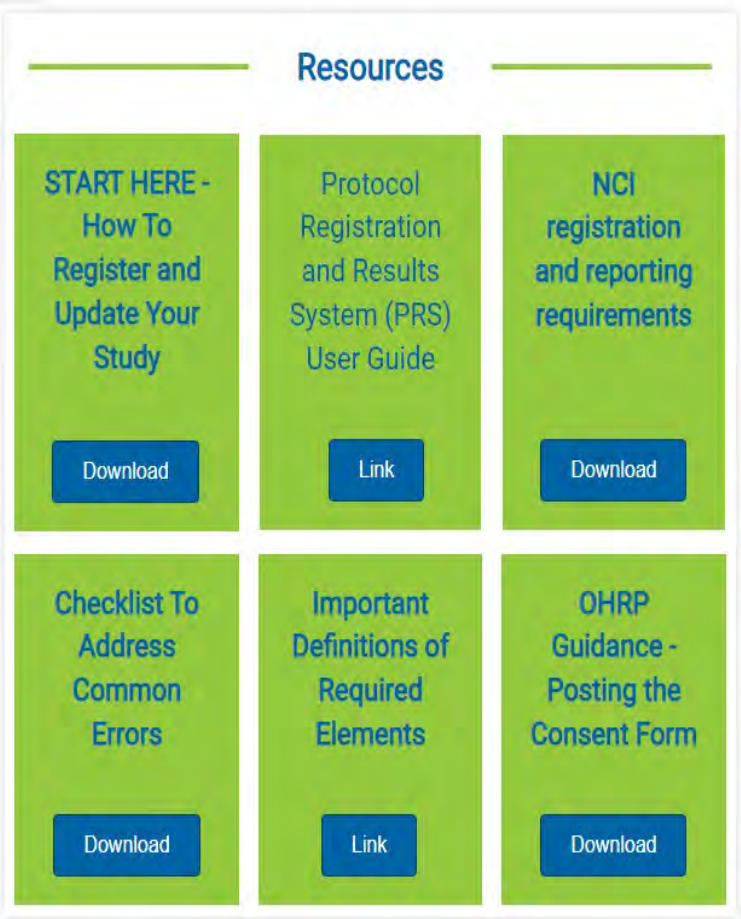
[Option #1: If the data and biospecimens are coded and can be linked back to the identity of the participant]
We will protect the confidentiality of your information to the extent possible. Your data and/or biospecimens will be coded to protect your identity before they are shared with other researchers. *[indicate which entity has the code key]* will have a code key that can be used to link to your identifying information. The code key will be securely stored. Future researchers must agree not to identify you.

[Option #2: If the data and biospecimens cannot be easily linked back to the identity of the participant]
Your name and identifying information will be removed from any data and/or biospecimens you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and/or biospecimens. Future researchers must agree not to identify you.

ClinicalTrials.gov Updates:

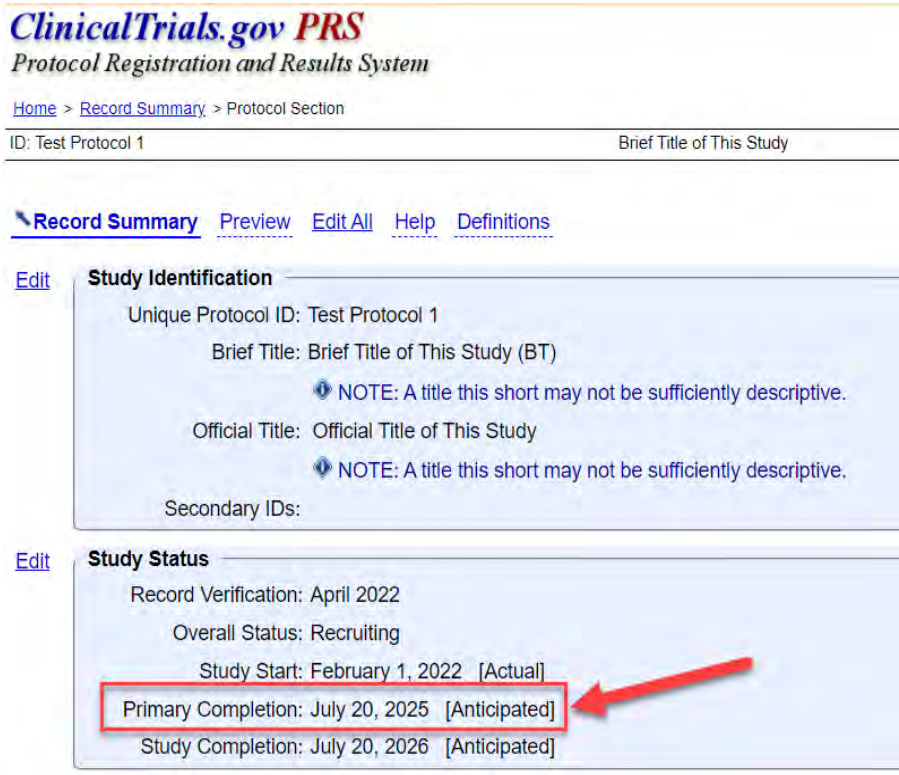
Registration may be required if one (or more) of the following is true:

1. Your study is **funded by the National Institutes of Health** (NIH) **AND** meets the **NIH definition** of a clinical trial [learn more...]
2. Your study involves **drugs, devices, or biologics** that are **regulated by the Food and Drug Administration** (FDA) and meets the definition of an **Applicable Clinical Trial (ACT)** [learn more...]
3. The study meets the International Committee of Medical Journal Editors **(ICMJE) definition of a clinical trial AND t**here is a plan to **publish the results in an ICMJE journal** [learn more...]
4. If your clinical trial will bill routine costs to **Medicare,** the study must be registered on ClinicalTrials.gov [learn more...]
5. If your **clinical trial receives funding** from **Department of Defense**, Patient-Centered Outcomes Research Institute **(PCORI)**, **National Cancer Institute (NCI)**, **Veterans Affairs (VA)** [learn more...]



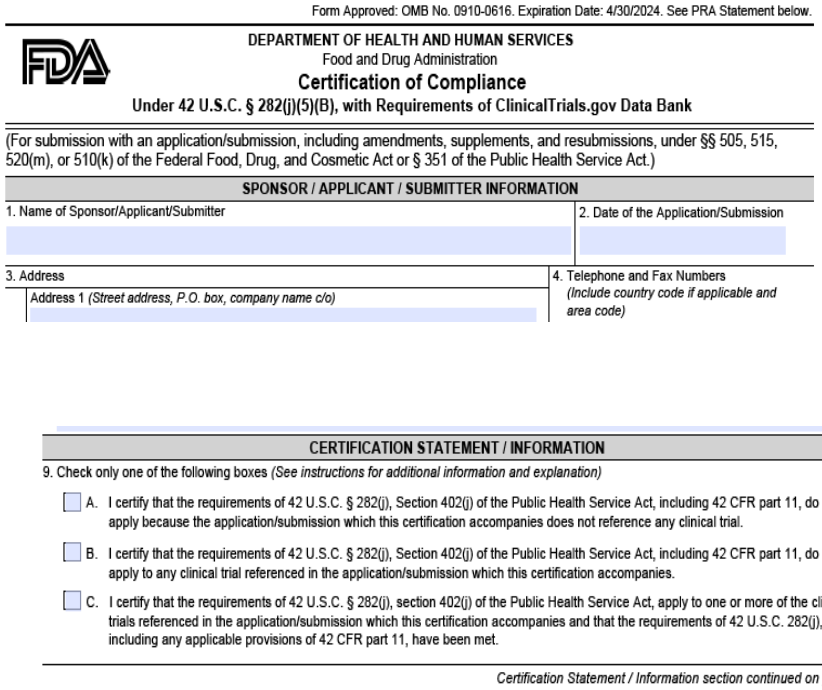
NIH Potential Non-compliance with Clinical Trial Results Information Submission Requirements

- In August of 2022, the **NIH Office of Inspector General (OIG)** performed an audit to determine **whether NIH ensured that NIH-funded clinical trials complied with Federal reporting requirements**.
- The published **report found that NIH did not ensure** all clinical trial results were reported in accordance with federal requirements and therefore **recommended that NIH take enforcement actions.**
- **The NIH is now issuing letters of potential non-compliance.**
- If your **NIH Funded Clinical Trial requires results reporting, remember:**
  - *Submission of results information is **required no later than 12 months after the Primary Completion Date (the last subject last visit)** of the clinical trial, which is defined as the date of final data collection for the primary outcome measure.*



Sponsor-Investigators submitting an IND, NDA, BLA, or 510k etc. application to the FDA

- **The FDA recommends that Form FDA 3674 accompany the submission.**
- Per instructions on Form FDA 3674, Sponsors must "***provide the NCT Number*** *obtained from www.ClinicalTrials.gov* ***for each applicable clinical trial*** *for which …****data is included, relied upon, or otherwise referred to****, in the application/submission which the certification accompanies.*"



Form Approved: OMB No. 0910-0616. Expiration Date: 4/30/2024. See PRA Statement below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
2. Date of the Application/Submission
3. Address
   Address 1 *(Street address, P.O. box, company name c/o)*
4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

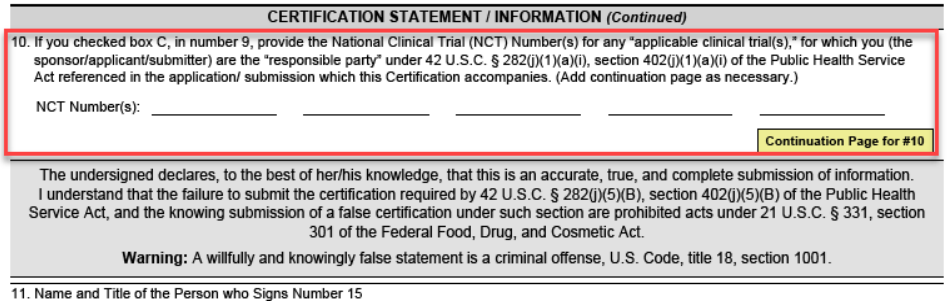
☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that the requirements of 42 U.S.C. 282(j), including any applicable provisions of 42 CFR part 11, have been met.

Certification Statement / Information section continued on page 2

Sponsor-Investigators submitting an IND, NDA, BLA, or 510k etc. application to the FDA

- **The NCT# section may be left blank (Box 10)** may be left blank if the submitter has checked Box 9.C but, at the time the certification is completed, the submitter has not yet received any NCT number(s) for the applicable clinical trial(s) for which data is included, relied upon, or otherwise referred to in the IND application.
- There is no requirement to register the study on clinicaltirals.gov at this time!
- The only **expectation for registration per FDA** is outlined in 42 CFR 11.24(a) which is no later than ***21 calendar days after the first human subject is enrolled***.
- Per UCI *HRP Policy#2*, **study recruitment** (which includes releasing the clinicaltrials.gov record) **may begin AFTER IRB approval**



CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," for which you (the sponsor/applicant/submitter) are the "responsible party" under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

10. National Clinical Trial (NCT) Numbers – If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from *www.ClinicalTrials.gov* for each applicable clinical trial for which the sponsor/applicant/submitter is the "responsible party" and for which data is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" for which data is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies and for which the sponsor/applicant/submitter is the "responsible party." Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT number(s) for the "applicable clinical trial(s)" for which data is included, relied upon, or otherwise referred to in the application/ submission. Use a continuation page only if you have filled in all available spaces.

Questions?

Anu Mathur
Education and Quality Improvement Program Administrator
Interim IRB-A and hSCRO Administrator
PRS Administrator (ClinicalTrials.gov)
anuradhm@uci.edu

Agenda

- Welcome
  - Research Security and Integrity Compliance
  - C&G Accounting Updates
  - Research Administrators United (RAU)
  - Award Setup Process
  - Human Research Protections (HRP) Updates
  - ***Clinical Trials Contracting Team***
  - DocuSign 700U
- Q&A and Closing

Clinical Trial Contracting

Tam Tran
Director, Clinical Trials
QRAM March 2023

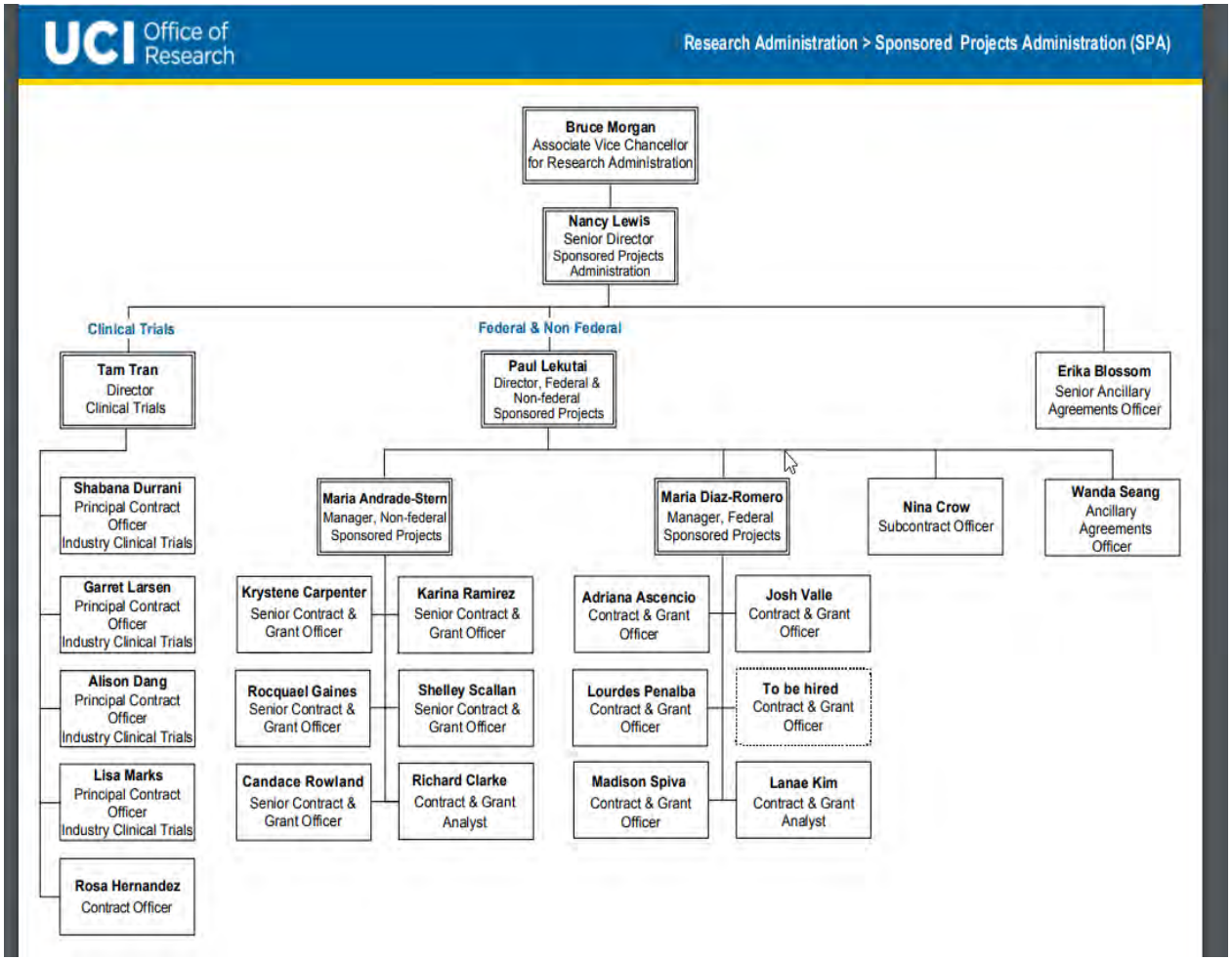
Staff Update

- Lisa Marks

Principal Contract Officer

- Rosa Hernandez

Contract Officer



Scope of Clinical Trials

Clinical Trial Contracting Team

- Industry
- Federal flow through to UCI from another entity
- CIRM flow through to UCI from another entity
- Non-profits

Federal Team

- Federally funded Clinical Trials awarded to UCI

Erika Blossom

- CIRM

Nonprofit Clinical Trials Process

Garrett K. Larsen
Principal Contract Officer
Clinical Trials Contracting

Nonprofit Clinical Trial Proposals

- Route CT proposals as you would for any other research proposal in KR, but ensure that you properly answer the questionnaire and compliance tab questions and list “Clinical Trial Research” as the activity type in the KR proposal.

- Give me/our team a heads up that it’s coming through via email to me (glarsen@uci.edu) or our central inbox OR-CTContracts@uci.edu. I will be the officer reviewing and signing off.

- Five days for review is standard but the more notice the better to ensure there are no last minute technical or legal issues.

Nonprofit Clinical Trial Agreements

- Reviewed and executed by the Clinical Trials Contracting team (and me specifically).
- KR Process is similar to industry CTAs.
- EXCEPT for any CT that requires a proposal to be submitted to a sponsor with a hard deadline as the KR doc will have already been routed and approved.

Contact us

Garrett K. Larsen – glarsen@uci.edu or on Teams

For our team – OR-CTContracts@uci.edu

Agenda

- Welcome
  - Research Security and Integrity Compliance
  - C&G Accounting Updates
  - Research Administrators United (RAU)
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  - ***DocuSign 700U***
- Q&A and Closing

DocuSign PowerForms for 700U

Barbara Inderwiesche

DocuSign PowerForms for 700U

- The forms are posted on two Office of Research websites:
  - https://research.uci.edu/conflict-of-interest/disc-req/coi-requests/
  - https://research.uci.edu/conflict-of-interest/coi-policies/

Disclosing individuals must disclose their financial interests received within the 12 months prior to the disclosure submission including the financial interests of their spouse/registered domestic partner, and/or dependent child(ren). All positive disclosures must be approved prior to the acceptance of the award/expenditure of funds and/or to the IRB approval of the protocol. Depending on the nature of the study and the sponsor(s), more than one conflict of interest disclosure policy may apply. Please check with the COI Team if you have questions.

Note: Non-UCI Researchers have different COI forms.

State Law | National Science Foundation | Public Health Service and Department of Energy | Human Subjects

Update: Two new fillable DocuSign versions of the Form 700U available.

- Principal Investigator Only Form 700U
- Department Administrator/Delegate and PI Form 700U

Reporting Triggers:

- Research contract/grant from a non-governmental entity
- Research gifts earmarked for a specific individual or a specific research project
- Material Transfer Agreement

Note: Exclude all exempt sponsors on FPPC approved list and all non-profit, tax-exempt educational institutions. However, researchers must disclose for the prime sponsor if the educational institution received its funds from a non-governmental entity.

Principal Investigator (PI) ONLY

- PIs should use this link to complete the entire Form 700U independently.
- The PI enters their name and email in the first two text boxes.
- ***OPTIONAL***: The PI may enter another name and email address in the last two text boxes for another individual to receive a copy of the completed 700U after the PI finishes signing. (eg. Their Department Administrator)

PowerForm Signer Information

Fill in the name and email for each signing role listed below.
Signers will receive an email inviting them to sign this document.

Please enter your name and email to begin the signing process.

Principal Investigator (PI)

Your Name: *

Barbara Inderwiesche

Your Email: *

barbara.i@uci.edu

Please provide information for any other
signers needed for this document.

Department Administrator (receives a copy)

Name:

My Department Administrator

Email:

barbara.i@uci.edu

PRINCIPAL INVESTIGATORS

A Public Document

Campus: _____

ID No: _____

Please type or print in ink.

Required - Last Name | (FIRST) | (MIDDLE) | TELEPHONE NUMBER

ACADEMIC UNIT OR DEPARTMENT | MAIL CODE | E-MAIL ADDRESS

TITLE OF RESEARCH PROJECT

1. Information Regarding Funding Entity

(Use a separate Form 700-U for each funding entity.)

Name of Entity:

Address of Entity:

Principal Business of Entity:

Amount of Funding: $

Estimated ◯ Actual ◯

2. Type of Statement (Check at least one box)

◯ Initial (for new funding)

Date of initial funding: ____/____/____

◯ Interim (for renewed funding)
Funding was renewed on: ____/____/____

3. Filer Information

A. Are you a director, officer, partner, trustee, consultant, employee, or do you hold a position of management in the entity listed in Part 1? No ◯ Yes ◯

Title: _____

B. Do you, your spouse or registered domestic partner, or your dependent children have an investment of $2,000 or more in the entity listed in Part 1 above?
No ◯ Yes ◯ – value is:

☐ $2,000 - $10,000 ☐ $10,001 - $100,000
☐ $100,001 - $1,000,000 ☐ Exceeds $1,000,000

Date Disposed: ____/____/____ if applicable

C. Have you received income of $500 or more from the entity listed in Part 1 during the reporting period?
No ◯ Yes ◯ – amount is:

☐ $500 - $1,000 ☐ $1,001 - $10,000
☐ $10,001 - $100,000 ☐ Exceeds $100,000

Was this income received through your spouse or registered domestic partner? ☐ No ☐ Yes

3. Filer Information – *Cont.*

D. Have you received loans from the entity in Part 1 for which the balance exceeded $500 during the reporting period?
No ◯ Yes ◯ – highest balance:

☐ $500 - $1,000 ☐ $1,001 - $10,000
☐ $10,001 - $100,000 ☐ Exceeded $100,000

If you checked "yes," was the loan:
☐ Secured ☐ Unsecured Interest rate: _____%

Was the loan entirely repaid within the last 12 months?
☐ No ☐ Yes

E. Have you received gifts from the entity listed in Part 1 within the last 12 months valued at $50 or more?
No ◯ Yes ◯ – describe below.

Description: _____

Value: $_____ Date Received: ____/____/____

F. Has the entity in Part 1 paid for your travel during the reporting period? No ◯ Yes ◯ – describe below.

Type of Payment: (check one) ☐ Gift ☐ Income

Amt: $_____ date(s): ____/____/____ ____/____/____
(If gift)

Description and, if Gift, Travel Destination: _____

4. Verification

I have used all reasonable diligence in preparing this statement. I have reviewed this statement and to the best of my knowledge the information contained herein and in any attached schedules is true and complete. I certify under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Date Signed 3/21/2023 (month, day, year)

Sign

Signature _____

(File the originally signed statement with your university.)

The Form 700-U is for university use only.
This statement is a public record under Gov. Code Section 81008(a).

Department Administrator / Delegate and PI

- Use this link if you are assisting the PI with completing the form.
- Enter your name and email as the Department Administrator in the first two text boxes and enter the PI's name and email address in the last two text boxes.
- After you complete the PI information and sections one and two, the form will route to the PI to complete and sign.
- After the PI completes and signs, you will receive the PDF copy by email.

UCI Office of Research
Research Administration

PowerForm Signer Information

Fill in the name and email for each signing role listed below.
Signers will receive an email inviting them to sign this document.

Please enter your name and email to begin the signing process.

Department Administrator

Your Name: *

Barbara Inderwiesche

Your Email: *

barbara.i@uci.edu

Please provide information for any other
signers needed for this document.

Principal Investigator (PI)

Name:

Principal Investigator

Email:

barbara.i@uci.edu

A Public Document

Please type or print in ink.

Campus: _____

ID No: _____

NAME (LAST)	(FIRST)	(MIDDLE)	TELEPHONE NUMBER
			( )

ACADEMIC UNIT OR DEPARTMENT	MAIL CODE	E-MAIL ADDRESS

TITLE OF RESEARCH PROJECT

1. Information Regarding Funding Entity

(Use a separate Form 700-U for each funding entity.)

Name of Entity:

Address of Entity:

Principal Business of Entity:

Amount of Funding: $

Estimated ◯ Actual ◯

2. Type of Statement (Check at least one box)

◯ Initial (for new funding)

Date of initial funding: ____/____/____

◯ Interim (for renewed funding)
Funding was renewed on: ____/____/____

3. Filer Information

A. Are you a director, officer, partner, trustee, consultant, employee, or do you hold a position of management in the entity listed in Part 1? No ☐ Yes ☐

Title: _____

B. Do you, your spouse or registered domestic partner, or your dependent children have an investment of $2,000 or more in the entity listed in Part 1 above?
No ☐ Yes ☐ – value is:

☐ $2,000 - $10,000 ☐ $10,001 - $100,000
☐ $100,001 - $1,000,000 ☐ Exceeds $1,000,000

Date Disposed: ____/____/____, if applicable

3. Filer Information - *Cont.*

D. Have you received loans from the entity in Part 1 for which the balance exceeded $500 during the reporting period?
No ☐ Yes ☐ – highest balance:

☐ $500 - $1,000 ☐ $1,001 - $10,000
☐ $10,001 - $100,000 ☐ Exceeded $100,000

If you checked "yes," was the loan:
☐ Secured ☐ Unsecured Interest rate: _____%

Was the loan entirely repaid within the last 12 months?
☐ No ☐ Yes

E. Have you received gifts from the entity listed in Part 1 within the last 12 months valued at $50 or more?
No ☐ Yes ☐ – describe below.

Description: _____

Value: $_____ Date Received: ____/____/____

F. Has the entity in Part 1 paid for your travel during the reporting period? No ☐ Yes ☐ – describe below.

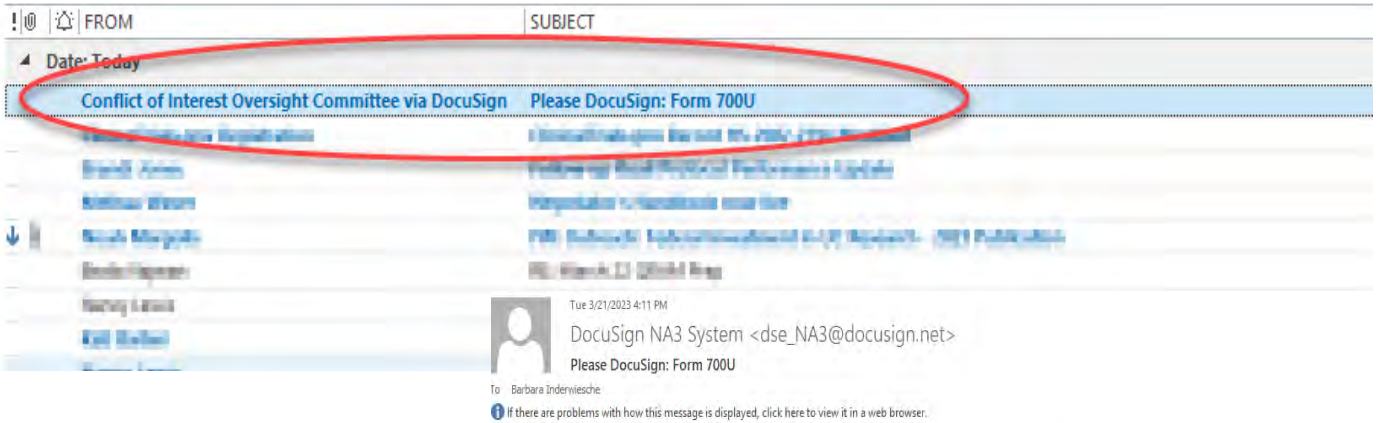
Type of Payment: (check one) ☐ Gift ☐ Income

Amt: $_____ date(s): ____/____/____ ____/____/____
(If gift)

Description and, if Gift, Travel Destination: _____

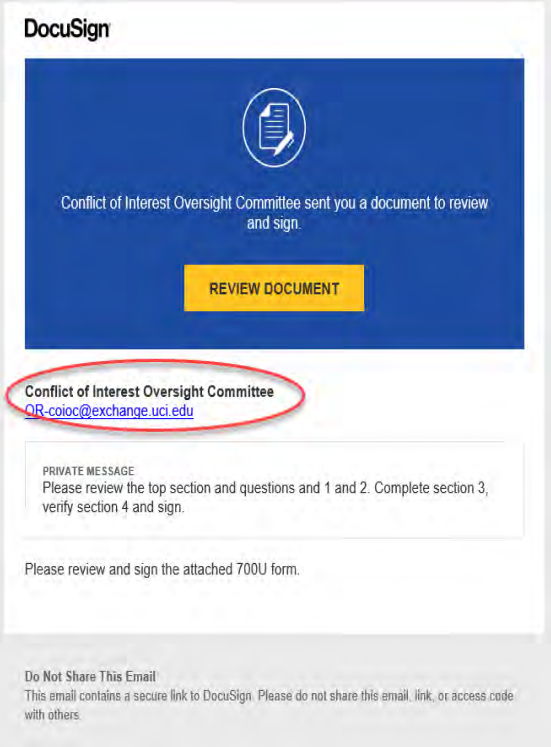
4. Verification

I have used all reasonable diligence in preparing this statement. I have reviewed this statement and to the best of my knowledge



Emails come from:
Conflict of Interest Oversight Committee via DocuSign
OR-coioc@exchange.uci.edu

**This is not a monitored email for purposes of DocuSign*



NAME (LAST)	(FIRST)	(MIDDLE)	TELEPHONE NUMBER
Investigator	Principal		( )
ACADEMIC UNIT OR DEPARTMENT	MAIL CODE		E-MAIL ADDRESS
12345 University Street			pi@company.com

TITLE OF RESEARCH PROJECT

This is the title of the research project

1. Information Regarding Funding Entity

(Use a separate Form 700-U for each funding entity.)

Name of Entity:
Cupcakes International

Address of Entity:
555 Sweet Drive

Principal Business of Entity:
Catering

Amount of Funding: $ 25,000

Estimated [X] Actual [ ]

2. Type of Statement (Check at least one box)

[X] Initial (for new funding)
Date of initial funding: 03 / 01 / 2023

[ ] Interim (for renewed funding)
Funding was renewed on: ____/____/____

3. Filer Information

A. Are you a director, officer, partner, trustee, consultant, employee, or do you hold a position of management in the entity listed in Part 1? No ◯ Yes ◯

Title: _____

B. Do you, your spouse or registered domestic partner, or your dependent children have an investment of $2,000 or more in the entity listed in Part 1 above?
No ◯ Yes ◯ – value is:

[ ] $2,000 - $10,000 [ ] $10,001 - $100,000
[ ] $100,001 - $1,000,000 [ ] Exceeds $1,000,000

Date Disposed: ____/____/____ if applicable

C. Have you received income of $500 or more from the entity listed in Part 1 during the reporting period?
No ◯ Yes ◯ – amount is:

[ ] $500 - $1,000 [ ] $1,001 - $10,000
[ ] $10,001 - $100,000 [ ] Exceeds $100,000

Was this income received through your spouse or registered domestic partner? [ ] No [ ] Yes

3. Filer Information - *Cont.*

D. Have you received loans from the entity in Part 1 for which the balance exceeded $500 during the reporting period?
No ◯ Yes ◯ – highest balance:

[ ] $500 - $1,000 [ ] $1,001 - $10,000
[ ] $10,001 - $100,000 [ ] Exceeded $100,000

If you checked "yes," was the loan:
[ ] Secured [ ] Unsecured Interest rate: _____%

Was the loan entirely repaid within the last 12 months?
[ ] No [ ] Yes

E. Have you received gifts from the entity listed in Part 1 within the last 12 months valued at $50 or more?
No ◯ Yes ◯ – describe below.

Description: _____

Value: $_____ Date Received: ____/____/____

F. Has the entity in Part 1 paid for your travel during the reporting period? No ◯ Yes ◯ – describe below.

Type of Payment: (check one) [ ] Gift [ ] Income

Amt: $_____ date(s): ____/____/____ ____/____/____
(If gift)

Description and, if Gift, Travel Destination: _____

4. Verification

I have used all reasonable diligence in preparing this statement. I have reviewed this statement and to the best of my knowledge the information contained herein and in any attached schedules is true and complete. I certify under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Date Signed: 3/21/2023 (month, day, year)

Signature Sign (File the originally signed statement with your university.)

The Form 700-U is for university use only.
This statement is a public record under Gov. Code Section 81008(a).

Completed 700U Forms

- No change to current process
- Forward completed 700U forms to SPA, ISR or Advancement (for gifts) either by request or through KR Proposal Development
  - Do NOT add your officers to the signer workflow

- FYI: Other Actions, Decline to Sign
  - If anyone selects this option, a notification will go to OR-coioc@exchange.uci.edu which is not monitored for DocuSign purposes.
  - If PI clicks Decline to Sign by mistake, create a new form.

Questions?

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Join us next time!

June 2023 (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