UCI Office of Research
Research Administration

Quarterly Research Administration Meeting

February 21, 2024

Agenda

- ***Welcome***
- Equipment vs Supplies
- Human Research Protections Updates
- Composite Fringe Benefit Rates for FY25
- Closeouts
- C&G Accounting Updates
- Data Classification
- New KR PD Personnel Role
- Q&A and Closing

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Equipment vs Supplies

Helen Chang
Equipment, Surplus Property and KFS Asset Manager
Procurement Services, Division of Finance and Administration

Equipment vs. Supplies

- ***Exempt from indirect cost (budget in Equipment category)***
  - Equipment over $5K, title remains with the University

- ***Not Exempt from indirect cost (budget in supplies category)***
  - Materials, supplies & low-value equipment
  - Equipment where the title remains the awarding agency
  - Equipment loaned back to the awarding agency
  - Equipment shipped to the awarding agency

Equipment vs. Supplies

- ***Pending Federal Awards Funding***
  - Must apply for “RAS” Request Advance Spending from the SPA
  - Must comply with federal funds purchase requirements
  - Cannot purchase equipment in advance with non-federal funds

Questions?

Helen Chang

hmchang@uci.edu

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UCI Office of Research

QRAM Winter 2024: Human Research Protections Updates

Anu Mathur, EQUIP / hSCRO Manager
Will Kettler, Minimal Risk Administrator

Non-Human Subject's Research and Exempt Self-determinations in KRP:

- **Reminder:** Per **HRP listservs sent on July 10, 2023, and February 14, 2024:** https://news.research.uci.edu/cg-news/updated-irb-and-hscro-forms-2/.
- Per instructions on the applications "***UCI IRB review is not required and will not be provided.***"
- **However, EQUIP Staff will continue to audit** these submissions for **QA** purposes:
  - Study teams may need to address Action Items in KRP.
  - If any Action Items relate to potential access to **PHI**, the recommendation is to stop the project until receipt of EQUIP email confirmation that the project can continue.
  - For any additional questions, please forward your inquiry to EQUIP at EQUIP@uci.edu.

KRP Application Update!

Efficiencies initiated by our own HRP staff William Kettler, Minimal Risk Administrator and Director Jessica Sheldon!

- **Waiver of HIPAA Authorization and waiver of Consent** are routinely requested to access medical records for:
  - 1) prescreening/recruitment activities
  - 2) chart reviews
- ***NEW***: ONE assurance prompt for Lead Researcher
- ***NEW***: Provide options for acceptable waiver justifications rather than free text responses
- Remove Yes/No questions and other prompts
- Reduces opportunity for inconsistency throughout form

Streamlined Form: Waiver or Alteration of Consent

Provide assurance that the research meets all of the waiver criteria listed below:

(i) The research involves no more than minimal risk to the subjects;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

- [x] As Lead Researcher, I assure all of the above waiver criteria are met – See 'Risk Assessment' & 'Confidentiality of Research Data' subsections for details

Explain why the research could not practicably be conducted without the waiver [45 CFR 46.116(f)(3)(ii)] (check all that apply):

- [ ] Disclosure of the study purpose as part of the consent process would bias the research subjects so that the results will not be meaningful.
- [x] Risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek consent.
- [ ] Risk of inflicting psychological, social or other harm by contacting individuals or families
- [ ] Sample size required is so large (e.g., population-based studies, epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed
- [ ] Subjects for whom records would be reviewed are no longer followed and may be lost to follow-up. For example the proportion of individuals likely to have relocated or died may be a significant percentage of the subject population and the research results may not be meaningful and lose statistical power
- [ ] Other scientifically and ethically justifiable rationale (explain)

Streamlined Form: Waiver of HIPAA

Provide assurance that the research meets all of the waiver criteria listed below:

- **The use or disclosure of personal health information involves no more than minimal risk to the privacy of individuals [45 CFR 164.512(h)(i)(2)(ii)(A)]:**
  - **(1) There is an adequate plan to protect the personal identifiers from improper use & disclosure**
  - **(2) There is an adequate plan to destroy the personal identifiers at the earliest opportunity or a research justification for retaining the identifiers**
  - **(3) PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted**
- **The research could not practicably be conducted without access to, use or disclosure of the personal identifiers listed in the PHI question & the PHI requested is the minimum necessary to meet the research objectives [45 CFR 164.512(h)(i)(2)(ii)(C)]**

☑ As Lead Researcher, I assure all of the above waiver criteria are met – See 'Risk Assessment' & 'Confidentiality of Research Data' subsections for details

Specify why the research could not practicably be conducted without the waiver [164.512(h)(i)(2)(ii)(B)] (check all that apply):

☐ Risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek consent

☐ Risk of inflicting psychological, social or other harm by contacting individuals or families

☐ Sample size required is so large (e.g., population-based studies, epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed

☐ Subjects for whom records would be reviewed are no longer followed and may be lost to follow-up. For example the proportion of individuals likely to have relocated or died may be a significant percentage of the subject population and the research results may not be meaningful and lose statistical power

☑ Other scientifically and ethically justifiable rationale (explain)

Clinicaltrials.gov

- The **FDA** has now *publicly posted* their Pre-Notices for Potential Noncompliance with ClinicalTrials.gov requirements.
- Due to an OIG audit, **NIH** has also ramped up sending notifications of potential non-compliance.

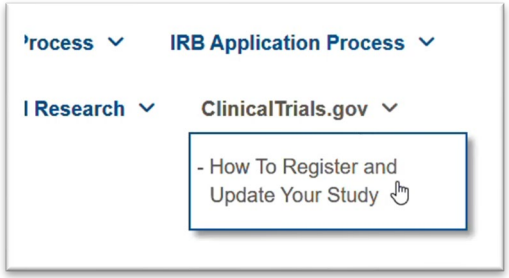
➢ **BOTTOM LINE**: It is critical that **all UCI ClinicalTrials.gov are accurate** and compliant.

➢ **HELP is available**!

Clinicaltrials.gov

- **HELP is available from the EQUIP / hSCRO team!**
  - *Anu Mathur, EQUIP / hSCRO Manager (anuradhm@uci.edu)*
  - *Kendrick Canizales, EQUIP / hSCRO Senior Analyst (kjcaniza@uci.edu)*

✓Updates to UCI HRP clincialtrials.gov website – now a stand-alone webpage!
✓Updated guidance – help with the registration and update process
✓Added ct.gov specific office hours Tuesday and Fridays!



Clinicaltrials.gov

➢ ***NEW!*** KRP Renewal Application Section - prompts researchers to update ct.gov record.

Confirm the accuracy of the information on the ClinicalTrials.gov Protocol Registration and Results System (PRS):

IMPORTANT! Per federal requirements (42 CFR 11.64(a)(1)(ii)), clinical trial registration information on PRS must be updated not less than once every 12 months.

Please review the information on PRS to verify that the following fields are accurate and up to date:

- Study Status:
  - Record Verification Date: Not less than every 12 months, enter the date on which the responsible party last verified the clinical study information on PRS, even if no additional or updated information was submitted.
  - Overall Recruitment Status: 30 calendar days after a change in overall recruitment status, enter the status for the clinical study as a whole, based upon the status of the individual sites. If at least one facility in a multi-site clinical study has a status of "Recruiting," then the overall status for the study must be "Recruiting."
  - Primary Completion Date: 30 calendar days after the clinical trial reaches its actual primary completion date, enter the date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes. IMPORTANT! This date cannot be in the past, please revise the date as necessary.
  - Study Completion Date: 30 calendar days after the clinical trial reaches its actual study completion date, enter the date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (for example, last participant's last visit), whether the clinical study concluded according to the pre-specified protocol or was terminated. IMPORTANT! This date cannot be in the past, please revise the date as necessary.
- Oversight:
  - Human Subjects Review Board Status: 30 calendar days after a change in status, ensure the status of IRB approval information is accurate.
- Contacts, Locations, and Investigator Information: 30 calendar days after a change, ensure the information is accurate.

☐ As leader researcher, I confirm that the clinical trial information (listed above) on PRS is accurate and up to date.

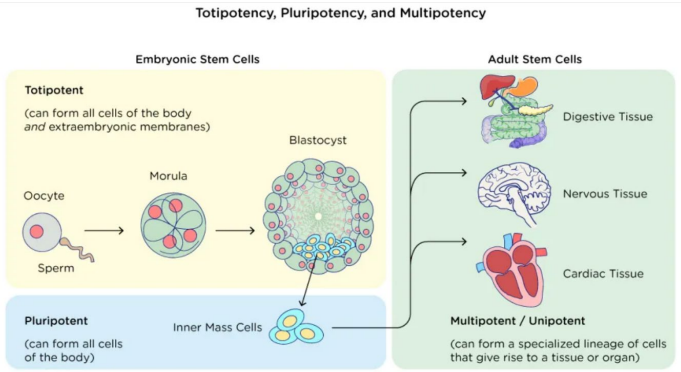
Human Stem Cell Research Oversight Committee Updates:

- hSCRO website updated for clarity
- Added hSCRO specific office hours
- First hSCRO listserv launched November 2023 to inform stem cell community about updates
- *Upcoming in 2024: Revisions to the* UCI hSCRO Policy and Standard Operating Procedures

Activities that require UCI hSCRO review:

All research or clinical investigations that involve the following activities:

- **Generation of new lines of human pluripotent stem cells** from whatever source and by whatever means.
- Use of:
  - **human gametes**
  - **human embryos**
  - **human induced pluripotent stem cells** (iPSC)
  - **human fetal tissue and/ or human fetal stem cells**
  - **human embryonic stem cells**
- Transplantation of **stem cells into humans** *(not including **Mesenchymal** or **Hematopoietic** stem cells)*.
- **Activities involving the introduction** of human adult pluripotent, human fetal tissue, human fetal stem cells, human embryonic stem cells, or their neural derivatives **into nonhuman animals** at any stage of embryonic, fetal, or postnatal development.
- Activities in which **the identity of the donors of blastocysts, gametes, or somatic cells** from which human stem cells were derived is readily **ascertainable or might become known to the investigator**.



UCI

QUESTIONS

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Composite Fringe Benefit Rates FY25

Nancy Lewis

Senior Director, Sponsored Projects Administration

Composite Fringe Benefit Rates (CBR) FY 24-25

- The Division of Finance and Administration has provided updated composite fringe benefit rates (CBR) for FY 24-25.
- The new rates and planning rates can be found on the Employee Fringe Benefits webpage on the Office of Research website.
- Effective February 12th, these rates should be used in proposals and revised budgets, as applicable.

Composite Fringe Benefit Rates (CBR) 24-25

Rate Table

Looking for Prior Rates? → Past Rates

		Approved by DHHS		For Planning Purposes Only (Subject to Change)				
		Campus Rates		Estimated Rates (for C&G)				
	Employee Groups	FY24	FY25	FY26	FY27	FY28	FY29	FY30
	For Employees with Full Benefits							
1	Faculty	32.60%	33.70%	34.71%	35.75%	36.82%	37.92%	39.06%
2	Other Academic	46.50%	45.40%	46.76%	48.16%	49.60%	51.09%	52.62%
3	Post Doc	19.50%	22.80%	23.53%	24.28%	25.06%	25.86%	26.69%
4	HCOMP Faculty/Physician (MSP)/Nurse/Law Faculty/Police	23.80%	27.60%	27.87%	28.71%	29.57%	30.46%	31.37%
5	Staff Exempt	46.50%	45.40%	46.76%	48.16%	49.60%	51.09%	52.62%
6	Staff Non-Exempt	52.00%	51.60%	53.15%	54.74%	56.38%	58.07%	59.81%
7	Food-Custodian-Grounds-Building Maintenance Workers	52.00%	51.60%	53.15%	54.74%	56.38%	58.07%	59.81%
	For Employees with Less than Full Benefits and Students							
8	Faculty Summer Salary	5.30%	8.70%	8.79%	8.88%	8.97%	9.06%	9.15%
9	Students and Employees with No Eligibility	2.00%	2.30%	2.32%	2.34%	2.36%	2.38%	2.40%
10	Partial Benefit Eligibility	2.00%	2.30%	2.32%	2.34%	2.36%	2.38%	2.40%

Questions?

Nancy Lewis
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Award Closeout

Beata Najman
Director, Extramural Funds Accounting

Definition

The closeout of a Federal award is the process in which the awarding agency determines that all applicable administrative actions and all required work have been completed by the recipient.

Uniform Guidance 2 CFR 200.344

- All financial, performance, and other required reports as required by the terms and conditions must be submitted to the awarding agency **no later than 120 calendar days after the end date of the period of performance.**
- Award recipient must liquidate all financial obligations incurred under the Federal award no later than 120 calendar days after the end date of the period of performance.
- **Subrecipients** are required to report final expenditures to pass-through entity **within 90 calendar** days.

Award Closeout Will Be Completed Even If the Recipient Doesn't Complete It!

- Federal awarding agency or pass through entity will close out the Federal award with the information available.
- **The Federal awarding agency has a closeout deadline and must complete closeout no later than one year after the end of the period of performance, and document timely closeout in grants management and payment systems.**
- Non-compliant award recipients may be subjected to the following:
  - Temporary withhold of cash payments
  - Audit disallowances
  - Suspension or termination of award (partial or full)
  - Subjected to suspension or debarment proceedings
  - Reported by the Federal agency in the integrity and performance system (currently FAPIIS).

NIH: New 90-Day Closeout Reminder Notification

- NIH recipients must submit a Final Federal Financial Report (FFR), Final Research Performance Progress Report (F-RPPR), and Final Invention Statement and Certification (FIS) within 120 calendar days of the end of the period of performance (project period), as required in section 8.6 of the NIH Grants Policy Statement.

- NIH previously sent reminder emails to recipients 10, 120, and 150 days after the project period end date.

- Effective January 2024, NIH has begun sending an additional reminder closeout email notification 90 days after the project period end date.

NIH Unilateral Closeout

Updated Process for Requesting Drawdowns Outside of the Liquidation Period

- After the 120-day liquidation period funds are no longer available to be drawn for the awards in Open or Pending Closed status.
- Without prior approval from the awarding Institute or Center (IC), **NIH will initiate unilateral closeout for all awards that fail to meet closeout requirements within 120 days.**
- Prior approvals for late cash draws may be granted in rare circumstances on a case-by-case basis, and only when cash draw delays are well justified.

NOT-OD-24-055, **Release date January 23, 2024**

If a recipient does not submit required reports within a year of the project end date, NIH will report unilateral closeout actions in SAM.gov retroactively, beginning with all unilateral closeout actions taken since January 1, 2023.

NSF Financial Close

NSF will financially close awards 120 days after the award end date and the award will be removed from the ACM$ payment screen for active awards. Awards funded with canceling funds have stringent reporting deadlines.

From: DFM Payments and Analytics Branch <dfmpab@nsf.gov>
Sent: Monday, February 19, 2024 8:05 AM
To: Griselda Duran <griseld@uci.edu>
Subject: NSF Award(s) with Canceling Funds
To: University of California-Irvine (Organization ID: 0013144000)
Subject: NSF Award(s) with Canceling Funds

Award ID	PI Name	Award Expiration Date	Canceling Amount	Non-Canceling Amount
17XXXXX	XXXXXXXXXXXXX	08/31/2024	$105,266.26	$0.00
17XXXXX	XXXXXXXXXXXXX	07/31/2024	$79,523.27	$0.00

Dear Awardee:

This email is to notify you that your organization has National Science Foundation (NSF) award(s) with appropriations that will be canceled this fiscal year. In accordance with 31 USC 1552(a), the appropriations will be canceled by the U.S. Department of Treasury after September 30, 2024, and will not be available for obligation or expenditure for any purpose thereafter.

Although the official canceling date is September 30, 2024, ACM$ will only be available for drawdown transactions until 2pm EDT on Monday, September 23, 2024, to allow 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, 2024, whichever comes first. However, you must drawdown these funds before the ACM$ deadline of 2pm on Monday, September 23, 2024. Failure to do so before the ACM$ deadline will result in the cancellation of those funds, and they will 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. Please review these awards and alert the appropriate principal investigator (PI), project director, or other project support staff for their attention.

Per the NSF Proposal and Award Policies and Procedures Guide (PAPPG), if only a portion of the awarded funds are canceling, then NSF will reduce the available balance of the award. If all funds under the award are canceling, then NSF must financially close the award no later than September 30th regardless of the project end date. No extensions, requests for payment, or upward adjustments will be allowed beyond the end of the fiscal year in which the funds cancel. Although in this situation awards may be financially closed early, awardees will still have the full 120-day closeout period to submit final project reports in accordance with the terms and conditions of the award. Awardees are cautioned against advancing remaining funds solely for the purpose of expending remaining balances. It is important to promptly return any excess funds that may have been drawn down.

If there are program or performance issues, the PI should contact their NSF Program Officer or Grants and Agreements Official as soon as possible. If the delay in activity is due to access issues with ACM$, or a financial issue such as a payment or expenditure problem, please contact your Grant Accountant.

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C&G Accounting Updates

Beata Najman
Director, Extramural Funds Accounting

Deficit Clearing Process – NEW in FY2024

DEFICIT DEFINITION

The amount by which final cumulative expenditures exceed the budget amount after final reconciliation by Contracts & Grants Accounting (CGA). This can be caused by:

- Expenditures beyond the authorized amount by the sponsor
- Non-payment by the sponsor even if expenditures are within original authorized amount
- Untimely posting of expenses at the end of the award or restricted budget period in which case CGA may only bill or draw cash for the final expenses per ledger.

If a fund is expecting an amendment or pending final transactions at 120 days, Departments need to inform CGA.

Deficit Clearing Process for C&G Awards with the End Dates in a Prior Fiscal Year (Award End Date before 7/01/2023)

By April 15th of each year, the Assistant Dean of each School will be provided with a list of awards requiring a deficit clearing during the current fiscal year, and will be required to confirm the deficit clearing option they prefer to be used for their School's C&G deficits.

The options available for the year-end C&G deficit clearing include:

Option 1

Clear C&G deficits to their continuation accounts. All deficits will be cleared by transferring direct expenses on C&G accounts to their continuation accounts. By May 31st, a detailed list of transfers and affected continuation accounts will be provided to each School that elected this option.

Option 2

Clear deficits as a reduction of the total overhead allocation for the current fiscal year, using no more than 2% of the overall overhead earned by the School for that year. C&G Accounting will transfer direct costs from the projects in deficits to a designated holding account, and in June of each year up to 2% of overall overhead brought in by the School during the fiscal year will be used to cover deficits in the C&G awards that ended before the start of that year.

Deficit Clearing Process Timeline

- Schools will be required to notify C&G Accounting which option they chose to use no later than **April 30th** of each year, and this will allow for all entries to be completed before the end of June of each year.

- In cases in which a response from the School is not received by the April 30th deadline, C&G Accounting will use Option 1 and complete the required cleanup before the **end of May**.

- All adjustments will be completed by C&G Accounting and this process is expected to continue on an annual basis.

Questions?

Beata Najman

bnajman@uci.edu

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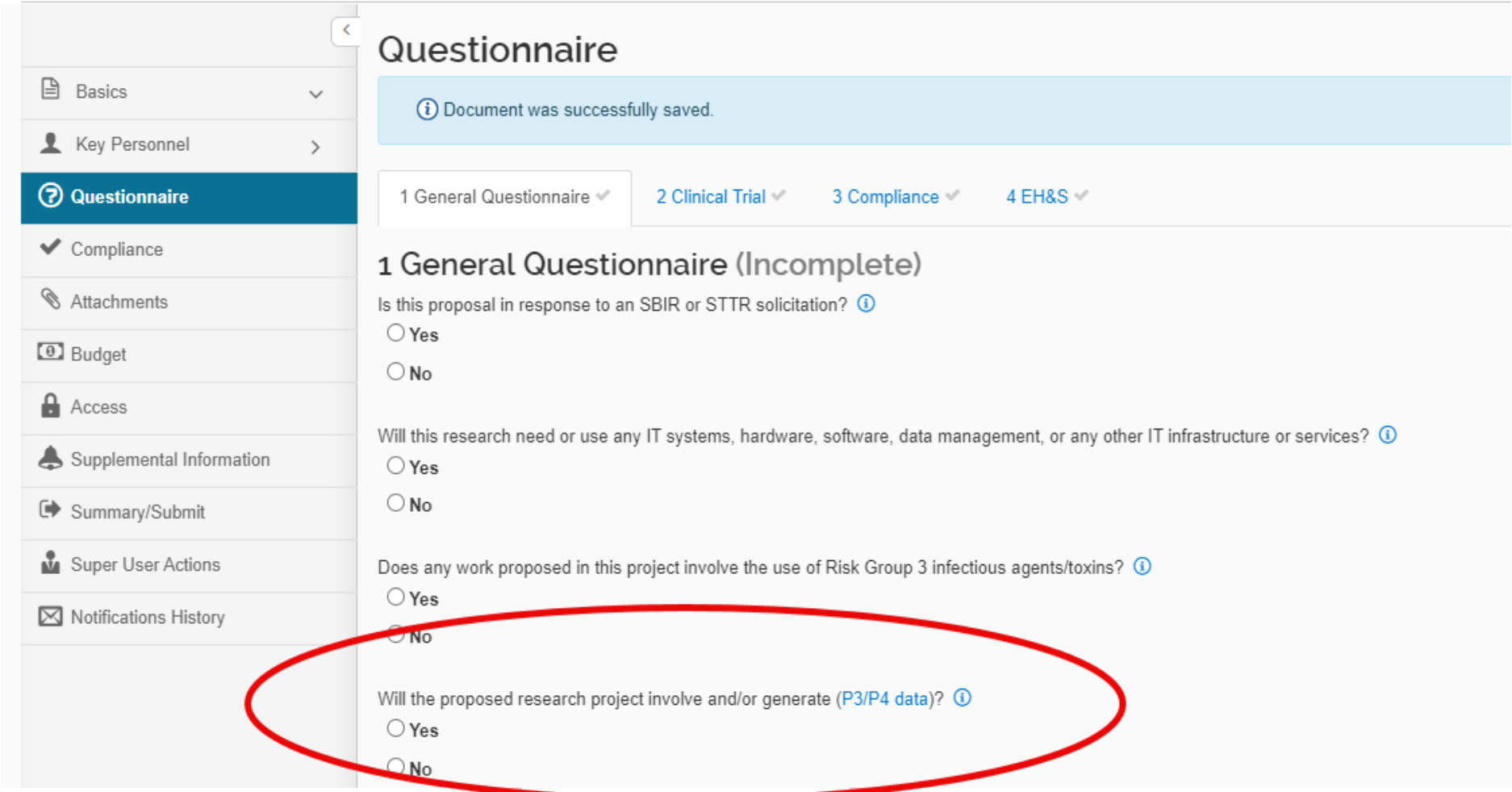
Data Classification

Grace Park
Director, Research Engagement and Compliance

Data Classification



Data Classification

Purpose: To safeguard sensitive sponsored research data

Resources

- OIT Protection Levels Webpage
- Contact UISL

Updated certification language in KR PD

By approving this proposal, I certify, to the best of my knowledge, that:

1. The information entered in the Kuali Research Proposal Development (KRPD) system regarding this proposal is true, accurate, and complete.
2. The information contained in the proposal application is true and accurate, and that I understand that any false, fictitious, or fraudulent statements or claims may subject the University and me, individually, to criminal, civil, or administrative penalties.
3. The information contained in the proposal application is complete and includes all information required in accordance with application guidelines and sponsor rules and policies, and that applicable university policies and guidance were followed in preparing the proposal application.
4. No UCI employee or appointee who is proposed to conduct the research is currently debarred, proposed for debarment, suspended, declared ineligible, or voluntarily excluded from transactions by any U.S. federal agency or entity.
5. If the proposal is to the U.S. federal government and the proposed research includes either human subject research or research using animals covered by either the US Department of Agriculture or U.S. Public Health Service policies, the IRB and/or IACUC protocol application(s) will be identical in principle and congruent with the UCI scope of work contained in the proposal.

I further certify, that I will comply with all applicable sponsor policies and regulations, university policies and guidance (including the UC Standards of Ethical Conduct and UC Contract and Grant Manual), and applicable law related to this sponsor's funding decision process.

In addition to the above, and if the proposal is funded, I certify and affirm that:

1. I accept responsibility for the design, ethical conduct, fiscal and administrative management, and reporting of this project, including submission of any required reports.
2. I will comply with the award terms and conditions, sponsor policies and regulations, university policies and guidance (including the UC Standards of Ethical Conduct and UC Contract and Grant Manual), and applicable law, and I will inform all other UCI employees, appointees, and students who will conduct the research project that the same is expected of them.
3. I and the research team will follow our unit's/units' data security management plan(s) if the sponsored research award involves P3 or P4 data.
4. I will submit or will have the protocol Lead Researcher(s) submit modifications and/or changes to the IRB and/or IACUC, as necessary and applicable, to assure the protocol(s) remain identical in principle and congruent with UCI's scope of work contained in the sponsored research award.
5. Space arrangements are in place to meet the proposed research project's space requirements.
6. The resources described in the proposal will be available to conduct the research project.
7. If any UCI employee, appointee, or student involved in conducting the research project becomes debarred or is proposed for debarment, or is suspended, declared ineligible, or voluntarily excluded from transactions by any U.S. federal agency or entity, that I will promptly report this to Sponsored Projects Administration upon becoming aware of this information.

Send Adhoc | Ad Hoc Recipients | Approve | Return | View Route Log | Recall | Submit to Sponsor | More Actions | Close

Questions?

Grace Park

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New KR PD Personnel Role for Federal Proposals and Flow-Through

Nadia Wong
Research Compliance & Outreach Manager
Research Security & International Engagement

Current KR PD Personnel Roles

- Principal Investigator
- PI/Contact
- PI/Multiple
- Co-PI
- Key Person
- Investigator (For projects with PHS, Dept. of Energy, NSF, and NASA as a sponsor or prime sponsor)
  - Individuals NOT required to submit a biosketch but meet the COI definition of an Investigator (responsible for design, conduct, or reporting of the project)

Other Significant Contrib. (Contributor)

- New KR PD Personnel Tab Role available February 28, 2024
- Use this KR PD Personnel role when the federal sponsor requires this UCI individual to submit a biographical sketch and other/current & pending support but the individual does NOT meet the COI definition of an Investigator.
  - This individual will receive a custom link to the RSIE questionnaire for the Federal Proposal Review to complete prior to the proposal submission to workflow.
  - There are no COI disclosure requirements for this individual.

KR PD Personnel Roles Table

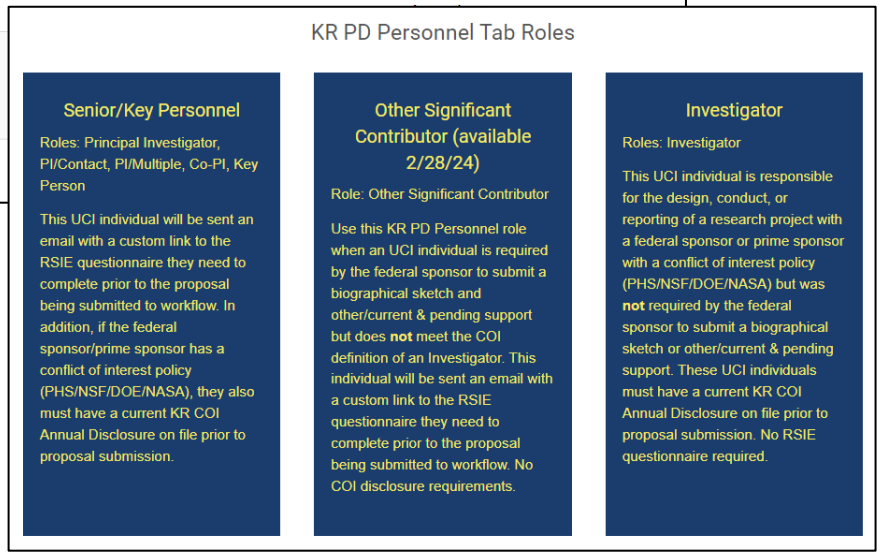
Federal Proposal Review	Conflict of Interest	KR PD Personnel Role(s)
Does the Federal sponsor/prime sponsor require a biographical sketch from this individual?	*Is the individual an "Investigator" (responsible for the design, conduct, or reporting of the project)?*	*Which KR PD Personnel Role should be used for that individual?*
Yes	Yes	**Principal Investigator; PI/Contact; PI/Multiple; Co-PI; or Key Person**
Yes	No	**Other Significant Contrib.** (available 2/28/24)
No	Yes	Federal sponsor/prime sponsor with COI Policy (PHS/DOE/NSF/NASA): **Investigator**
		Federal sponsor/prime sponsor without COI policy: **Do not include the individual in the KR PD Personnel tab**
No	No	**Do not include the individual in the KR PD Personnel tab**

Resources

- Updated websites
  - Federal Proposal Review
  - Requests from COI
    - Under Other > Kuali Research Proposal Development Personnel Tab Roles

From the Federal Proposal Review page:

Federal Proposal Review *Does the Federal sponsor/prime sponsor require a biographical sketch from this individual?*	Conflict of Interest *Is the individual an "Investigator" (responsible for the design, conduct, or reporting of the project)?*	KR PD Personnel Role(s) *Which KR PD Personnel Role should be used for that individual?*
Yes	Yes	**Principal Investigator, PI/Contract, PI/Multiple, Co-PI, or Key Person**
Yes	No	**Other Significant Contributor** (available 2/28/24)
No	Yes	Federal sponsor/prime sponsor with COI Policy (PHS, DOE, NSF, and NASA):
No		
No		



Questions?

Nadia Wong

nadiaw@uci.edu

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- ***Q&A and Closing***

-2024 QRAM Schedule –

~~02/21/2024~~
05/15/2024
08/21/2024
12/11/2024

All on Wednesdays from 10:00AM-11:30AM