Quarterly Research Administration Meeting

September 13, 2023
Agenda

• Welcome
  – FY 23 Award Dollars - FY 23
  – Honest Broker - Cohort Discovery Tools
  – Federal Update
  – RSIC Process Review
  – COI Update – Clinical Trial Procedure Notification Method
  – ERA Updates
  – C&G Accounting

• Q&A and Closing
Breakouts

• Name
• Department / School / Area
• How long have you been at UCI?
• Preference: Coffee, Tea, or Soda?
• What kind and from where?
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• Q&A and Closing
Honest Broker
(a part of the wider Data Steward role...)

Andrea Hwang, MS, MBA
Clinical Research Informatics Lead
Enterprise Data & Analytics, Information Services
UCI Health

Fall QRAM, 9/13/2023
Agenda

1. Honest Broker, defined

2. Data provisioning for research purposes
   2.1 What types of UCI Health data are available*?
   2.2 How to request such data?
      A. Cohort Discovery (the Cohort Discovery Tool, TriNetX)
      B. Approvals*
      C. Submit a service ticket
   2.3 How are data requests triaged?
   2.4 How is data disclosed?

3. Perspective

* Materials adapted from the virtual workshop presentation by Dr. Kai Zheng (Chief Research Information Officer, Health Affairs) on September 24th, 2021
1. Honest Broker, what and who

“An individual, organization or system acting for, or on behalf of, the covered entity to collect and provide health information to researchers in such a manner whereby it would not be reasonably possible for the investigators or others to identify the corresponding patients-subjects directly or indirectly.” – UPMC Honest Broker Policy, 2007

“…I see the Honest Broker as the intermediary between the covered entity and the researchers…” – Karen Allen (email correspondence)

What the Honest Broker is NOT:

- Honest Broker can not be one of the researchers
- Honest Broker is not Privacy Officers nor IRB Staff
- Honest Broker must abide by the “Common Rule” (45 CFR Part 46) and the HIPAA Privacy Rule (45 CFR Parts 160, 164), but they are not responsible for conveying or interpreting policies

The department of Enterprise Data & Analytics in UCI Health, Information Services serves as the UCI’s institutional “Honest Broker” (HDGC Data Steward & IRB-approved protocol HS# 2012-8757, PI: David Merrill)

- Partner with ICTS/CBMI and Office of Research Information to fulfill data requests.
- In addition to de-identified data sets, the Data Steward also provisions limited data sets and identifiable data sets (containing PHI).
2. Data provisioning for research purposes
2.1 What types of UCI Health data are available for research reuse?

<table>
<thead>
<tr>
<th>Structured EHR Data</th>
<th>Social Determinants of Health</th>
<th>Free-Text Clinical Narratives</th>
<th>Operational Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic demographics, clinical encounters, vital signs, diagnoses, medications, lab tests, procedures, etc., of ~800k UCI Health patients since ~2010</td>
<td>Basic demographics, census tract-level community vital signs, and other geotag-based socioeconomic data (ArcGIS Enterprise)</td>
<td>Admission notes, progress notes, discharge summary, etc.</td>
<td>Check-in time, check-out time, whether the patient has an account with the MyChart Patient Portal and # of logins, etc.</td>
</tr>
<tr>
<td>Biospecimens</td>
<td>Imaging Data</td>
<td>Biosignal Data</td>
<td>UC Health Data Warehouse</td>
</tr>
<tr>
<td>Experimental Tissue Resource</td>
<td>3M+ images since 2000, Center for Artificial Intelligence in Diagnostic Medicine</td>
<td>Various data archives from bedside physiological devices</td>
<td>Fully de-identified structured EHR data across the UC</td>
</tr>
<tr>
<td>Delia Tifrea <a href="mailto:dltifrea@uci.edu">dltifrea@uci.edu</a></td>
<td>Peter Chang <a href="mailto:changp6@hs.uci.edu">changp6@hs.uci.edu</a></td>
<td>Health Affairs Office of Research Information <a href="mailto:ori@uci.edu">ori@uci.edu</a></td>
<td>Health Affairs Office of Research Information <a href="mailto:ori@uci.edu">ori@uci.edu</a></td>
</tr>
</tbody>
</table>

University of California - Irvine
2.2 How to request such data?

Step A. Perform cohort discovery

– Use the **Cohort Discovery Tool (powered by i2b2) or TriNetX** to perform data query and analysis of anonymous clinical data to characterize patient groups

– Take a hypothetical Inflammatory Bowel Disease (IBD) study as an example*:

    • **Inclusion & Exclusion criteria:**
      - Both Crohn’s Disease or Ulcerative Colitis
      - Age 18-80
      - Patients on corticosteroid therapy
      - Patients are Humira naïve
      - Exclude patients with CRP >= 5 mg/L
      - Must have NOT had endoscopy in last year

    • **This is a good example study as it demonstrate the following:**
      - **Diagnosis:** Crohn’s Disease/Ulcerative Colitis
      - **Demographic Limit:** Age 18-80
      - **Medication:** Corticosteroid therapy
      - **Medication:** Humira naïve (shows common name mapping – Humira vs. Adalimumab)
      - **Lab Value:** CRP >= 5mg/L (shows range)
      - One **Temporal Event – Procedure** (endoscopy)

– Consult with the Honest Broker to:
  - Specify the requested data elements
  - Assess feasibility of obtaining data electronically

* Example courtesy of Katie Genuario, ORI
2.2 How to request such data? (con’t)

Step B. Obtain (ALL) Approvals
- **De-identified data set** - Submission of a Non-Human Subject Research (NHSR) determination to the IRB is not required. PIs may simply complete the NHSR determination form then keep it on file, and the Education and Quality Improvement Program (EQUIP) will do a periodic audit to verify accuracy.

- **Limited data set** – A signed UCI Health DUA is required. Like de-identified data set, submission of a NHSR determination to the IRB is not required. EQUIP will do a periodic audit to verify accuracy.

- **Identifiable data set (containing PHI)** – An IRB approval is required.
2.2 How to request such data? (con’t)

Step C. Put In a Service Ticket

- EDA the “Honest Broker” (HDGC Data Steward & IRBapproved protocol HS# 20128757)
  - https://it.health.uci.edu/Enterprise-Data/requestdata.asp

- Office of Research Information (limited data from the UCI Health Clinical Data Warehouse, aka “LDS OMOP”)
  - ori@uci.edu
2.3 How are data requests triaged?

Since the Honest Broker is only permitted to disclose data within the approved scope, a request is reviewed vis-à-vis the protocol to ensure congruence between the request, approvals, and the protocol.

In Kuali Research Protocol:

a. Project Procedures > Medical Records specifies that UCI Health medical records will be obtained from “UCI Health Enterprise Data & Analytics (HDGC Data Steward & IRB approved protocol HS# 2012-8757)”

b. Subject Population(s) > Eligibility Criteria specifies inclusion/exclusion.

c. Project Procedures > Data Points specifies data elements.
   • Date-range
   • Data Abstraction Form

d. Sample Size
2.4 How is data disclosed or released?

• Deliver data sets to the secure location: Protected Virtual Computing Environment (PVCE)
  – The data can only be exported out of PVCE, with permission from the CRIO, as long as one of the following 3 conditions is met:
    1. researchers must submit the data to a third party (e.g., the NIH, the CDC), provided that proper data transfer agreement and HDGC approval are in place
    2. researchers need to export the data into another HIPAA-compliant system (e.g., REDCap, Qualtrics) for valid reasons (e.g., to support participant recruitment, to administer patient surveys)
    3. the protected virtual computing environment is not adequate to accommodate the storage or computing needs (e.g., dataset is too large, analytical tools required are too specialized, requiring GPU processing)

• Track each data disclosure
  – Including request date, information about the researcher, IRB documentation, disclosure authorization type, delivery date, and the delivered datasets.
  – HIPAA disclosure accounting for studies with (partial) HIPAA waivers.
3. Perspective, and a Brave New Future

The Honest Broker has served more than 300 research protocols across more than 70 departments (e.g., CoHS, UCI Health, CCR, CC, Bio Sci, Phy Sci, Business) in the University since 2012.

Leverage current technology advancement to empower researchers and expedite discovery.

- Epic Nebula, Epic's next generation cloud analytics platform
  - Self-service tools (e.g., SlicerDicer)
  - Research data enclaves
- UCI Institute for Precision Health’s end-to-end data platform Syntropy (powered by Palantir Foundry)
- Data democratization
Thank You!

Questions? Email Andrea Hwang at ychwang@hs.uci.edu
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Federal Update

Maria Diaz Romero
Manager, Federal Sponsored Projects
NIH Update
Terminology Change: Funding Opportunity Announcement (FOA) to Notice of Funding Opportunity (NOFO)

- NIH is aligning with 2 CFR 200.204 (Uniform Guidance) and will now refer to our grant opportunities as Notices of Funding Opportunities (NOFOs) and phasing out use of the term Funding Opportunity Announcements (FOAs).

- You will see both NOFO and FOA during the transition period in NIH documents and communication.

- NOT-OD-23-109: Updates to Funding Opportunity Terminology was published on April 21, 2023.
Post Submission Materials Policy: For Applications Submitted After May 25, 2023 Receipt Date

NIH will accept a one-page update with preliminary data as post-submission material for the application types listed in the table below.

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Type 1 (New and Resubmission of New application)</th>
<th>Type 2 (Renewal)</th>
<th>Type 3 (Competitive Revision)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>Allowed*</td>
<td>Not allowed</td>
<td>Not allowed</td>
</tr>
<tr>
<td>R21</td>
<td>Allowed*</td>
<td>Not allowed</td>
<td>Not allowed</td>
</tr>
<tr>
<td>R03</td>
<td>Allowed*</td>
<td>Not allowed</td>
<td>Not allowed</td>
</tr>
<tr>
<td>All others</td>
<td>Not allowed</td>
<td>Not allowed</td>
<td>Not allowed</td>
</tr>
</tbody>
</table>

*Only if the NOFO allows preliminary data

Learn more: [NOT-OD-23-106](#)
Clinical Trials: Good Cause Extension Request Process and Criteria

- **NOT-OD-23-080** was implemented on February 15, 2023, to inform the research community that NIH has issued the *Clinical Trials Results Information Submission: Good Cause Extension Request Process and Criteria* document
  - Outlines the process and criteria for requesting a good cause extension of the submission deadline for clinical trial results information under 42 CFR 11.44(e) of the Final Rule for Clinical Trials Registration and Results Information, section 402(j)(3)(E)(vi) of the Public Health Service Act, and the complimentary NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information ([NOT-OD-16-149](#))
  - Extension requests must be submitted electronically via the ClinicalTrials.gov Protocol Registration and Results System (PRS) prior to the date that results information would otherwise be due (i.e., the primary completion date + 12 months)
    - Must include a description of the reason(s) that the responsible party believes constitute good cause to justify an extension and an estimated date on which the results information will be submitted

Learn more: [NOT-OD-23-080](#)
Redesigned xTrain Module Deployed

- A redesign of the xTrain module in eRA Commons was released on March 30, 2023.
- The xTrain module was redesigned to streamline workflows and present a more user-friendly interface, following extensive collaboration with both internal and external user groups.
- The module also has the new visual appearance of other eRA modules along with added security and stability.
- **Highlights for xTrain External Users**
  - Enhanced Trainee Roster with a display of awarded slots and counts of the in-progress forms
  - Enhanced screen for business officials with a list of all forms routed to them
  - An updated screen for trainees

Learn more: NOT-OD-23-094
NIH Policies for NRSA Stipends, Compensation and Other Income

- On April 21, 2023, NIH released NOT-OD-23-111, Reminder for NRSA Stipend, Compensation and Other Income.

- NIH stipends awarded to NRSA fellows and trainees are considered as subsistence allowance intended to help defray living expenses during the research training experience.

- Stipends cannot be provided as a condition of employment with either the Federal government or the sponsoring institution (Refer to NIH Grants Policy Statement 11.2.9.2 and 11.3.8.2).

Learn more: NOT-OD-23-111, 42 CFR Part 66
NIH Application Instruction Updates: Data Management and Sharing (DMS) Costs

• Updates the NIH application instructions for submitting requests for Data Management and Sharing costs in a single line item.

• Effective for applications submitted for due dates on or after October 5, 2023, NIH will no longer require the use of the single DMS cost line item.

• DMS costs must be requested in the appropriate cost category, e.g., personnel, equipment, supplies, and other expenses, following the instructions for the R&R Budget Form or PHS 398 Modular Budget Form, as applicable.

Learn more: NOT-OD-23-161
PAPPG (NSF 23-1): Safe and Inclusive Working Environments for Off-Campus or Off-Site Research

• For each proposal that proposes to conduct research off-campus or off-site, the AOR must certify that the organization has a plan in place for that proposal regarding safe and inclusive working environments.

• Off-campus or off-site research is defined as data/information/samples being collected off-campus or off-site, such as fieldwork and research activities on vessels and aircraft.

• The plan does not need to be submitted to NSF as part of the proposal.
PAPPG (NSF 23-1): Safe and Inclusive Working Environments for Off-Campus or Off-Site Research - FAQs

• How does NSF define off-campus or off-site?
  • It is the proposing organization’s responsibility to establish what constitutes an off-campus or off-site location.

• How do collaborative proposals comply with this requirement?
  • If more than one collaborating organization proposes to conduct research off-campus or off-site, one joint plan must be developed, unless otherwise specified in a program solicitation.

• Must the plan be in place prior to proposal submission?
  • Yes, the language contained in the certification was carefully crafted to require that the organization has a plan in place for that proposal that describes how the types of behavior specified in Chapter II.E.9 will be addressed.
PAPPG (NSF 23-1): Safe and Inclusive Working Environments for Off-Campus or Off-Site Research

UCI’s Template Plan can be found at research.uci.edu:
Revisions to the Biographical Sketch and Current and Pending (Other) Support

• Revision of the Biographical Sketch and Current and Pending (Other) Support
  • The revised formats are targeted for implementation in FY24.
  • Includes requisite certification regarding information being accurate, current and complete
  • ORCID use is encouraged
Senior Personnel Document Certification

• Senior personnel must certify that the information is accurate, current and complete.
  • In SciENcv the certification is completed upon download of the document.
  • For the fillable formats, the senior personnel must type their name and date on the form. NSF does not allow for certification via DocuSign or other comparable products.
PAPPG (NSF 23-1): Biographical Sketch and Current and Pending (Other) Support

• Both SciENcv and NSF fillable formats may be used through October 20, 2023.

• Use of SciENcv only will be mandated for proposals submitted or due on or after October 23, 2023.
Fastlane Decommission

- **Friday, September 29, 2023** (5:00 PM local time) is the last day to **submit** proposal file updates and budget revisions in FastLane, **withdraw** FastLane submitted proposals, and **withdraw** supplemental funding requests submitted in FastLane.

- **Friday, September 29, 2023** (11:00 PM Eastern Time) is the last day to **access** FastLane submitted and in-progress letters of intent, proposals, and supplemental funding requests.

- FastLane submitted and in-progress letters of intent, proposals, and supplemental funding requests **will not** be transferred to Research.gov; however, the reviews and summaries for proposals submitted in FastLane will remain available in Research.gov.

- **Friday, September 29, 2023** (11:00 PM Eastern Time) is the last day to access the FastLane Proposals, Awards and Status tab; Research Administration tab; and Honorary Awards tab on the FastLane homepage. These tabs will be removed from the FastLane homepage as of September 30, 2023, and the functionality will be decommissioned in FastLane.
NSF Project Reporting System Enhancements

- Effective July 24, 2023, the National Science Foundation (NSF) made enhancements to the Project Reporting System in Research.gov to enable datasets and research materials to be entered as distinct product types that are managed and reviewed separately.
- This change improves project report data quality by listing each product type resulting from NSF funded research as a separate entry rather than a combined listing of multiple product types.
- Other changes include improved system messaging and an updated user interface to provide a more seamless look and feel for NSF award recipients.
Updated NSF RCR Training Requirement

• **New:** For NSF proposals submitted on or after July 31, 2023, all faculty and other senior personnel on the proposal must complete RCR Training before the funding is awarded.

• Postdocs, grad students and undergraduates are still required to complete RCR training before conducting NSF-supported research.

• RCR training module can be found at uclc.uci.edu. Search “RCR” to access the module.

• Notice regarding this new requirement was sent to all UCI personnel on September 6, 2023 via Zotmail.
Updated NSF RCR Training Requirement - Zotmail

CHIPS and Science Act
New Responsible Conduct of Research (RCR) Training Requirements

We are writing to alert you to a change in the NSF’s requirements for education in the responsible conduct of research (RCR) that was prompted by the CHIPS and Science ACT of 2022. The CHIPS and Science Act requires NSF to take steps to strengthen research security and integrity for the federally funded research community. As a result, NSF has revised its requirements for education in the responsible conduct of research (RCR). NSF currently requires that postdoctoral scholars and students supported on NSF grants receive RCR education.
Updated NSF RCR Training Requirement - Zotmail

Principal Investigators and all other senior personnel (i.e., faculty and other academic appointees) supported on new NSF grants that result from proposals submitted on or after July 31, 2023, will also be required to complete RCR training.

The UCI RCR course is posted on the UCLC site (https://uclc.uci.edu/) and is accessible to the campus community using single sign-on. Upon entering the UCLC site, please search “RCR” to access the course. We encourage you and other senior personnel supported on your NSF grants to take the course as soon as possible if you haven’t done so already. Additional information and resources for training in the Responsible Conduct of Research at UC Irvine is available at https://research.uci.edu/rcr-and-research-misconduct/.

If you have questions regarding this requirement, please contact:

Jill Kay, Director, Research Policy at jill.kay@uci.edu.
Nancy Lewis, Senior Director, Sponsored Projects Administration at nrlewis@uci.edu or Paul Lekutai, Director, Federal and Non-Federal Sponsored Projects at plekutai@uci.edu.
Questions?
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RESEARCH SECURITY AND INTEGRITY
COMPLIANCE (RSIC)

QRAM- September 13, 2023

Nadia Wong
Research Compliance & Outreach Manager
FEDERAL FUNDING PROPOSAL REVIEW

To comply with federal sponsor expectations and proposal requirements, implement an institutional review that compares biographical sketch and other/current & pending support information with UC OATS and conflict of interest disclosures.

• Changes at proposal submission
  • All senior/key personnel on federal proposals (including federal flow-throughs) must answer questions about international engagements, activities, and affiliations in KR PD.
  • Questionnaire must be completed by the senior/key person themselves by signing into KR using their UCInetID prior to submitting PD into workflow.
  • For positive responses - Contracts & Grants Officers (CGO) will compare responses to information in the proposal and discrepancies must be resolved before submitting the proposal to the sponsor
  • KR will notify the REC team on all positive responses to begin a risk analysis
Encourage your faculty to update their biographical sketches and other/current & pending support **now** and make sure to disclose all international activities, relationships, research, etc.

Send the researchers a [preview of the questionnaire](#) so they can prepare.

List senior/key personnel in KR PD as soon as possible to initiate the notification process.

Confirm KR PD list of senior/key personnel matches the list included in the proposal application to sponsor.

If you see any positive responses, confirm the biosketches and if applicable other/current & pending support are in final form in KR PD and match the responses to the questionnaire.

If you experience or anticipate any problems with the senior/key personnel completing the questionnaire in time for the proposal submission deadline, please contact your CGO immediately.
IDENTIFICATION AND NOTIFICATION

1. Create a proposal in KR PD and include the sponsor and if applicable, prime sponsor

2. List senior/key personnel and investigators
   - List must match the list included in the proposal application to sponsor

<table>
<thead>
<tr>
<th>Senior/Key Personnel (includes PI)</th>
<th>Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition: individuals who contribute to the scientific development or execution of a project in a substantive measurable way</td>
<td>Definition: individual responsible for design, conduct, or reporting of the funded project</td>
</tr>
</tbody>
</table>

**Disclosure requirements**
- Submit biographical sketches and other/current & pending support
- Complete new RSIC questionnaire
- Submit disclosure for conflict of interest in research for PHS, DOE, NSF proposals (including flow-throughs)
- Not required to submit biographical sketches and other/current & pending support
- Not required to complete new RSIC questionnaire
- Submit disclosure for conflict of interest in research for PHS, DOE, NSF proposals (including flow-throughs)
IDENTIFICATION AND NOTIFICATION

3. Click “Notify All” button to generate notification email with custom direct links for senior/key personnel. The individual who generates the notification will be copied on the email.

• This button can send notifications multiple times for follow-up requests.
CHECK QUESTIONNAIRE STATUSES

Check completion status and click "View" to see if there are any positive responses.

Note: The Initiator will receive a KR email once all senior/key personnel have completed the questionnaire.
CHECK QUESTIONNAIRE STATUSES

For any positive responses, the biographical sketch and other/current & pending support will be reviewed by CGO to ensure these foreign activities, affiliations, relationships are appropriately disclosed to the federal sponsor.
If CGO discovers any missing documents and/or any discrepancies between the positive responses and the biographical sketch and if available, other/current & pending support, the proposal will be returned to the Initiator/department administrator and the requested revisions will be included in the notes. Discrepancies must be resolved prior to proposal submission to sponsor.

For positive responses, CGO must have access to final biosketches and if appliable, other/current & pending support in KR PD to conduct their review.
Changes at just-in-time/award stage

- When there is a positive response and other/current & pending support are not included in the initial application, CGO will request those documents to review for any discrepancies with the questionnaire responses.

- CGO will notify the REC team of the collection of any additional documents and/or if the proposal is still pending RSIC review

- REC team will review any additional documents collected and complete the RSIC review

- Award will not be released until CGO receives clearance from the REC team

To comply with federal sponsor expectations and proposal requirements, implement an institutional review that compares biographical sketch and other/current & pending support information with UC OATS and conflict of interest disclosures.
For positive disclosures, promptly provide copies of other/current & pending support to CGO when requested.

Confirm the other/current & pending support disclosures match the positive responses ("Yes's") in the questionnaires.
OTHER RSIC NEWS

• NSF requires SciENcv for biosketches and current & pending support starting October 23, 2023

• NASA’s final COI policy (Implementation December 1, 2023)- similar to NSF disclosure process

• Develop and implement a Research Security Program to comply with the final NSPM 33 Research Security Program Standard Requirement
  • Will likely require significant changes in foreign travel procedures
  • Implement Research Security training
  • Expand Export Control training audience
  • Ensure compliance with 12 baseline cybersecurity requirements

• Conflict of Commitment policies and UC OATS being updated (implementation July 2024)
Federal Funding Proposal Review

To meet the federal government’s expectations of institutions that receive federal research funds, UCI must ensure all Senior Key Personnel disclose complete and accurate information about their international engagements in compliance with federal agency disclosure requirements. This expectation applies to federal proposals, including subaward proposals where a federal agency is the prime sponsor (collectively referred to as federal proposals).

Meeting this expectation and complying with the federal agency disclosure requirements is essential for ensuring that UCI remains eligible to receive federal research funds.

Kuali Research Proposal Development (KRPD) includes six questions regarding international engagements that all Senior Key Personnel must answer before federal proposals are routed to Sponsored Projects Administration (SPA) for institutional review, approval, and submission. International engagements include, but are not limited to, employment, appointments, consulting activities, participation in foreign talent recruitment programs, and research support funding from foreign sponsors not received through UCI.

If any questions are not answered, therefore, proposal investigators, their support staff, and department/unit staff should take this into consideration in planning proposal submission timelines.

### Questions

| + Are you employed by a foreign entity? |
| + Are you a consultant (paid or unpaid) for a foreign entity? |
| Do you hold an academic appointment (including as honorific or merit-based title) or have an academic affiliation with a foreign entity? |
| Are you currently participating in, have you been accepted into, or do you have an application pending with a foreign government talent recruitment program or a similar program? |
| Does any proposal to a foreign government research funding entity include support or funding for you that will not be received through UCI? |
| Do you have research support or funding from a foreign government research funding entity that was not received through UCI? |

### Key Definitions

- **Foreign Entity**: A foreign entity is any foreign government (including any agency or subdivision), or any corporation, business association, partnership, trust, society, or any other entity or group that is not incorporated or organized to do business in the United States.

- **Consultant**: For the purposes of these questions, “consultant” broadly refers to an individual that provided or provides any service to a foreign entity, whether unpaid or paid, whether or not there is an agreement for the service performed. Disclose these activities unless specifically excluded by the federal sponsor (see Federal Sponsor Disclosure Requirements).

- **Foreign Government Talent Recruitment Program**: A foreign government talent recruitment program is an effort organized, managed, or funded by a foreign government or entity to recruit science and technology professionals to promote, advance, and/or increase the prestige and global impact of that country’s research enterprise.

- **Foreign Government Research Funding Entity**: A foreign government research funding entity is any non-U.S. government (or component thereof) that supports research projects by awarding
## Questionnaire

**Question**

**Are you employed by a foreign entity?**
If Yes, please include all current foreign employment in your biosketch submitted with this proposal, and please provide the following for each employer:
- Position title,
- Employment percentage, and
- Foreign entity name and country.

**Corresponding RSIC Disclosure(s)**
Biographical sketch

**Are you a consultant (paid or unpaid) for a foreign entity?**
“Consultant” broadly refers to an individual that provided or provides a paid or unpaid service to a foreign entity whether or not there is a written agreement for the service performed.
If Yes, please include all current consultancies in your biosketch submitted with this proposal, and please provide the following for each consultancy:
- Nature or purpose, and
- Foreign entity name, and country.

**Corresponding RSIC Disclosure(s)**
Biographical sketch
# Questionnaire

## Question

<table>
<thead>
<tr>
<th>Question</th>
<th>Corresponding RSIC Disclosure(s)</th>
</tr>
</thead>
</table>
| Do you hold an academic appointment (including an honorific or merit-based title) or have an academic affiliation with a foreign entity? If Yes, please include all foreign academic appointments or affiliations in your biosketch submitted with this proposal, and please provide the following for each appointment and/or affiliation:  
  • Appointment title or nature/purpose of affiliation, and  
  • Foreign entity name and country.                                                                                                           | Biographical sketch                                 |
| Are you currently participating in, have you been accepted into, or do you have an application pending with a foreign government talent recruitment program or a similar program?  
If Yes, please disclose your foreign government talent recruitment program status in your biosketch and/or current and pending support forms (in accordance with the sponsor’s application requirements) submitted with this proposal, and please provide the following:  
  • Program name  
  • Foreign entity name and country, and  
  • participation start and end dates.                                                                                                          | Biographical sketch  
Other/Current & Pending Support |
### Does any proposal to a foreign government research funding entity include support or funding for you that will not be received through UCI?

If Yes, please disclose any such proposals in your Current and Pending Support/Other Support form for this proposal, and please provide the following for each pending proposal:

- Project title,
- Foreign governmental sponsor,
- Your role on the project, and
- Project dates.

<table>
<thead>
<tr>
<th>Question</th>
<th>Corresponding RSIC Disclosure(s)</th>
</tr>
</thead>
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<tr>
<td>Does any proposal to a foreign government research funding entity include support or funding for you that will not be received through UCI?</td>
<td>Other/Current &amp; Pending Support</td>
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</table>

### Do you have research support or funding from a foreign government research funding entity that was not received through UCI?

If Yes, please disclose this research funding or support in your Current and Pending Support/Other Support form for this proposal, and please provide the following for each research award:

- Project title,
- Foreign governmental sponsor,
- Your role on the project, and
- Project dates.

<table>
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<tr>
<th>Question</th>
<th>Corresponding RSIC Disclosure(s)</th>
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<tr>
<td>Do you have research support or funding from a foreign government research funding entity that was not received through UCI?</td>
<td>Other/Current &amp; Pending Support</td>
</tr>
</tbody>
</table>
PART 1: STEPS REQUIRED PRIOR TO SUBMISSION TO SPONSOR

Initiator: Creates new federal funding proposal

Initiator: Adds PI and all Senior/Key Personnel to Personnel tab

Initiator: Sends email to all Senior/Key Personnel to complete certification questions by clicking “Notify All”

Certification questions completed by all Senior/Key Personnel?

Yes

No

Initiator: Sends reminder email(s)

Initiator: Receives email notification all certifications completed

Initiator: Submits to workflow

Yes

No

Does draft proposal include biosketches and if applicable, current & pending support in final form in KR PD?

Yes

No

Initiator: Uploads draft proposal with biosketches and if applicable, current & pending support in final form

Initiator: Contacts individual to request revision

No

CGOs: Notify Initiator of any discrepancy

Yes

CGOs: Complete institutional review process and submit application to sponsor

Note: Research Engagement & Compliance team will also review KR PD information with UCI records for risk and discrepancies and notifying appropriate parties of any concerns.

Key

CGOs: Contracts & Grants Officers

KR PD: Kuali Research Proposal Development

*Make sure KR PD list matches with proposal application list
PART 2: STEPS REQUIRED FOR THE RELEASE OF AWARD

Applies to proposals where other/current & pending support was not required with proposal submission

Key:
- CGOs: Contracts & Grants Officers
- KR PD: Kuali Research Proposal Development
- REC: Research Engagement & Compliance
# CONTACTS

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<th>Compliance Area</th>
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<td>Research Security and Integrity</td>
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<td><a href="mailto:rsic@uci.edu">rsic@uci.edu</a></td>
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<tr>
<td>Conflict of Interest in Research</td>
<td>Researchers' outside financial interest</td>
<td><a href="mailto:coioc@research.uci.edu">coioc@research.uci.edu</a></td>
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<td>Sponsored Projects Administration</td>
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<td>Beall Applied Innovation</td>
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<td>Digital Persistent Identifiers</td>
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Agenda

• Welcome
  – FY 23 Award Dollars - FY 23
  – Honest Broker - Cohort Discovery Tools
  – Federal Update
  – RSIC Process Review
  – **COI Update – Clinical Trial Procedure Notification Method**
    – ERA Updates
    – C&G Accounting

• Q&A and Closing
COI Update – Clinical Trial Procedure Notification Method

Jennifer Chen
Research Engagement and Compliance Analyst
COI Procedure for Clinical Trial Study

• Maintain standard procedure but with the following changes:
  o Once a positive disclosure is verified and the needed documents/information is collected (reference “what does COI need to start review”), the team (CCR, Stem Center, Cancer Center) will send an email to @OR - ORA - Conflict of Interest Oversight Committee and copy or-ctcontracts@uci.edu with the following information:
    ▪ KRP Number and/or Proposal Number
    ▪ Sponsor name
    ▪ Team member assigned to this study that can help facilitate communication between COI and DI. (Please note that approval emails and/or follow up emails to the disclosing individual will have the noted team member assigned in the cc)
  • CCR: designated team involved in the study (Neuroscience Team, Ophthalmology and Medicine Team, Surgical Specialty Team, Multi-Specialty Team)
  • Stem Center: designated team assigned to the study with additional cc of alphaclinregulatory@hs.uci.edu
What does COI need to start review

(\textit{In order of importance})

1. (IRB) KRP application start
   a. The KRP application does not need to be submitted to the IRB, but the application must be started to obtain the KRP #, which needs to be provided to the COI Team.
   b. The following section(s) should be as completed and accurate as possible:
      i. Study Team
         1. List of all study team members (if known)
         2. Disclosure of study team members
         3. Responsibilities / duties
      ii. Project Description
         1. Principal Investigator/Lead Researcher
         2. Funding
         3. Research Procedures / Study Design
         4. Medical Devices (if applicable)


3. Completed 700U (DocuSign)

Coming Soon…. (start date to be determined)

For questions or clarifications, please contact Jennifer Chen (jennic14@exchange.uci.edu)

COI Website Link
Questions?
Agenda

• Welcome
  – FY 23 Award Dollars - FY 23
  – Honest Broker - Cohort Discovery Tools
  – Federal Update
  – RSIC Process Review
  – COI Update – Clinical Trial Procedure Notification Method
  – **ERA Updates**
  – C&G Accounting

• Q&A and Closing
ERA Updates
KR Protocols (KRP) Release

• Kuali released 2 major updates for KR Protocols
  – Download All Attachments
  – Protocols Validations

• ERA updated KRP user guide accordingly
  – https://research.uci.edu/electronic-research-administration/kuali-research/kr-protocols/

• ERA sent listserv regarding these updates.
Download All Attachments

• All files in the Attachment List Section can now be downloaded as a single zip file.
• A new “Download All” button has been added next to the “Columns” button in Attachments.
Download All Attachments

• When the user clicks on the “Download All” button, all files will be zipped
  – New zip file will download automatically.
  – The zipped file will include the protocol number, version number and date/time it was downloaded.

• When unzipping the files, the attachment type will prefix the actual filename:
  “Recruitment Material – Recruitment Flyer.pdf”
Protocols Validations

• Click 'Notify PI To Submit' runs form validations first to alert you of any errors you may want to correct.
Protocols Validations

- A popup window will identify any validation errors, if any.

![Popup window example](image.png)
Protocols Validations

• Choose 'Show me' - the popup will close, and you can review the validation errors on the form.

⚠️ It may take a while to finish running the validation. Please do not click around until it finishes.

⚠️ Sometimes it does not lead to the errors even after running it through. You may have to scroll through to locate the errors from the beginning of the page.

• If you choose 'Notify PI Anyways', the notification will send to the PI anyway without addressing the errors and PI will need to address them.
Questions?
Research News

- NCURA YouTube Tuesday – Conflict: Part 2 of 3, Common Mistakes with Conflict
- Upcoming QRAM – Agenda and Zoom Info
- Upcoming QRAM – Agenda and Zoom Info
- NASA Grants and Cooperative Agreements Training Opportunity (training for our external stakeholders)
- NCURA YouTube Tuesday – Conflict: Part 1 of 3, Common Causes of Conflict

Research Tools & Support

Sponsored Projects
- KR Action List
  Click to see all your KR action requests
- KR Document Search
  Search any Kuali document type using document ID
  TIP: Filter with "Document Type"

Research Protections
- Training and Education
  Info for required CITI courses and tutorials
- Tutorial Verification Search
  Check training records status
- Protocol Status Search
  Check approved protocols status "UPDATING"
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OR Decision Support

Multi-Year Funded Awards
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<td>Reorganization of the Central Visual System by Inhibitory Neuron Transplantation</td>
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<td>Spatial epigenetics: A new framework for overcoming mechanical heterogeneity in solid tumors</td>
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<td>VICTOR JOE</td>
<td>Use of NeuroStrip for Treatment of Acute deep partial and full thickness Burn Injuries</td>
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<td>XINGMIN XU</td>
<td>Neural circuit mechanisms underlying AD-related memory impairments</td>
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<td>HRSA American Rescue Plan Act Funding for Health Centers</td>
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<td>The laminar organization of ‘index’ versus ‘attribute’ coding in neocortex</td>
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<td>TRANSLUCENCE BIOSYSTEMS LLC</td>
<td>003170 - NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)</td>
<td>MELISSA LODOEN</td>
<td>Rapid Evaluation Of Neuronal Activity In The Intact Whole Brain At Single Cell Resolution</td>
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<td>SUNIL GANDHI</td>
<td>A Computational Framework for Distributed Registration of Massive Neuroscience Images</td>
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<td>ERIC MJOLNESS</td>
<td>Multiscale theory of synapse function with model reduction by machine learning</td>
<td>08/01/2021</td>
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</table>
Research Administration Decision Support

Reports and data analysis tools for the UCI research enterprise.

Please note: These tools require UCI VPN for off-campus access.

**DWQuery**
- Contracts/Grants Ad Hoc Query
  - Instructions on using Contracts/Grants Ad Hoc Query
- For questions related to Sponsored Projects data, please contact era@research.uci.edu

**Award Activity**
- Awards by Campus Area
- Awards by Source by Campus Area
- Personnel Awards Credit by Role
- Daily Award Transactions

**Proposal Activity**
- Proposals by Campus Area

[https://research.uci.edu/electronic-research-administration/research-administration-decision-support/](https://research.uci.edu/electronic-research-administration/research-administration-decision-support/)
Daily Award Transactions

This will house the Daily Award Transactions Dashboard. This is updated at the end of each day, so this information reflects previous days' transactions.

To view the details of an award transaction, hover over the award amount on the right.

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Feedback needed
Agenda

• Welcome
  – FY 23 Award Dollars - FY 23
  – Honest Broker - Cohort Discovery Tools
  – Federal Update
  – RSIC Process Review
  – COI Update – Clinical Trial Procedure Notification Method
  – ERA Updates
  – C&G Accounting

• Q&A and Closing
C&G Accounting Has Moved to a New Address

University of California, Irvine
228 Aldrich Hall
Irvine, CA 92697-1050
C&G Training

COURSE #1 (CGS 1) Introduction to Fund Management
Thursday, October 26, 10:30 a.m. – 12 p.m.

COURSE #2 (CGS 2) Direct vs. F&A
Tuesday, October 31, 10:30 a.m. – 12 p.m.

COURSE #6 (CGS 6) Ledger Reading and Award Closeout
Thursday, November 2, 10:15 a.m. – 12 p.m.

Available in UCLC as an e-Course
COURSE #3 (CGS 3) General Error Correction (GEC)/Cost Transfers
COURSE #4 (CGS 4) Payroll Certification
COURSE #5 (CGS 5) Cost Sharing
Questions?
Questions?

Barbara Inderwiesche
barbara.i@uci.edu
OR
era@research.uci.edu
Join us next time (next year)!  
January 2024 (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