Quality Research Administration Meeting

August 30, 2017
Agenda

- Announcements
- Industry Sponsored Research
- Contracts and Grants Accounting Update
- Federal Update
- Research, Engagement and Facilitation (REF) Update
- Clinical Trials Update
- ClinicalTrials.gov/NIH Clinical Trial Definitions
- Electronic Research Administration (ERA) Update
- PI Exception Policy
- Revisions to Proposal Submission Guidelines
- Data Warehouse
OR-SPA list serv

• OR-SPA CG-News

• We will migrate all OR-SPA Subscribers to CG-News

• Timeline: Week of September 5, 2017
Certified Research Administrator (CRA) Exam Review Session

• **What:** RACC Body of Knowledge Review Session
• **When:** Monday, October 9, 2017 9:00AM-5:00PM
  – 8:30AM: Coffee and tea are served
• **Where:** University of California, Irvine
  – 845 Health Sciences Road
    Thorpe Conference Center, 4002 Gross Hall
• **Cost:** $225 for review session
• **Why:** Professional recognition, personal satisfaction, an indicator of expertise, increased opportunities for employment, advancement opportunities, increased credibility with clients, serve as a role model to others

For more information and to register, please visit: [http://www.cra-cert.org/appforreview.htm](http://www.cra-cert.org/appforreview.htm).
Office of Research YouTube Channel

• The UCI Office of Research YouTube Channel exists to host informative videos for UCI Faculty and Staff that help explain research policy and procedures, including tutorials on navigation through Electronic Research Administration (ERA) systems

• Video library
  – Cayuse 424
  – KC Conflict of Interest
  – Public Access Compliance
  – Coming soon…Export Control, Subrecipient Monitoring, IRB Reliance, and more!

• Subscribe Today!
Agenda

• Announcements
• **Industry Sponsored Research**
• Contracts and Grants Accounting Update
• Federal Update
• Research, Engagement and Facilitation (REF) Update
• Clinical Trials Update
• ClinicalTrials.gov/NIH Clinical Trial Definitions
• Electronic Research Administration (ERA) Update
• PI Exception Policy
• Revisions to Proposal Submission Guidelines
• Data Warehouse
Industry Sponsored Research (ISR) team

• Director
  – Kevin Kennan

• Industry Contract Officers:
  – Chris Abernethy
  – Angie Karchmer
  – Natalie Nodianos

• Industry Research and Material Transfer Officer:
  – Kelly Carlson
Who handles what?

Industry Sponsored Research

Angie
- School of Medicine

Chris
- Biological Sciences
- Beckman Laser Institute
- Physical Sciences

Natalie
- School of Engineering
- School of Information & Computer Sciences

Industry Sponsored Research/ Material Transfer

Kelly
- Entire Campus
Transition to Applied Innovation

• Campus units responsible for funding:
  – ISR: Industry (except clinical trials)
  – Office of Research: All other funding sources

• 2015: Transition of industry funding to Applied Innovation
Funding can come in a variety of ways, both directly and as flow-through, which ISR handles if there is any industry involvement:

- **Federal agency to company to UCI**
  - Department of Energy
  - General Atomics
  - UCI

- **Company to another university to UCI**
  - Pfizer
  - University of Southern California
  - UCI

- **Direct funding from industry:**
  - Dow DuPont
  - UCI
Agreement types handled by ISR

- Industry sponsored research agreements
- SBIR (Small Business Innovation Research Program)/STTR (Small Business Technology Transfer Program) subcontracts
- Other federal flow-through subcontracts
- Confidentiality and non-disclosure agreements
- Unfunded collaboration agreements
- Data use agreements
- Material transfer agreements
What is a material transfer agreement (MTA)?

• A contract to govern the transfer of research materials between organizations:
  – transfer between academic institutions
  – transfer from industry to UCI
  – transfer from UCI to industry
MTAs: Typical transfers and issues

- Materials transferred:
  - biological material
  - pharmaceutical compound
  - data
  - computer software

- Potential issues in MTAs:
  - confidentiality
  - delay in publication
  - conflicts with existing agreements
  - loss of control of intellectual property
  - compliance issues similar to industry research agreements
Contact Information

Industry Sponsored Research (ISR)

Chris Abernethy
Industry Contract Officer
(949) 824-1749
cabernet@uci.edu

Angie Karchmer
Industry Contract Officer
(949) 824-0341
angie.karchmer@uci.edu

Natalie Nodianos
Industry Contract Officer
(949) 824-8109
natalie.nodianos@uci.edu

Kelly Carlson
Material Transfer Officer
(949) 824-9223
kelly.carlson@uci.edu

http://innovation.uci.edu/about/industry-sponsored-research/
Agenda

- Announcements
- Industry Sponsored Research
- **Contracts and Grants Accounting Update**
- Federal Update
- Research, Engagement and Facilitation (REF) Update
- Clinical Trials Update
- ClinicalTrials.gov/NIH Clinical Trial Definitions
- Electronic Research Administration (ERA) Update
- PI Exception Policy
- Revisions to Proposal Submission Guidelines
- Data Warehouse
Contracts and Grants Accounting Update

Beata Najman
C&G Accounting Organizational Updates

• Revised Organizational Chart
• New Staff Members
• C&G Training
• Institutional Financial Contacts for Proposals
  ➢ Federal, CIRM and Special State – please list Beata Najman
  ➢ Private Grants and Contracts, and most MCAs - please list Mary (Gigi) Bones
  ➢ Federal Flow-through, State, Local and Other Government – please list Alice Han

• Financial Contacts for Current Awards – KFS, C&G website
C&G Write-offs of Disallowed Charges

- Lack of funding to cover C&G disallowed costs
- Monthly AR aging analysis and a review of invoices not paid for 90 days or more
- C&G Accounting collection efforts communicated with the award Fiscal Officers and departmental managers, and recorded in a log
- Budget reduction and AR reversal processed on a quarterly basis
- Budget and AR accounting entries will be reversed if funds are received
C&G Accounting Important Reminders and Process Updates

Problem:
Reporting and invoicing delays due to a lack of information from departments (including lack of cost sharing reports).

Solution:
1. E-mail #1 with a clear timeline and deadline
2. E-mail #2 with a Cc to a supervisor and with a final deadline
3. E-mail #3 with Cc to the PI and others previously emailed and a confirmation that if there is no reply, this is what C&G Accounting is reporting to the Sponsor.*

*Some exceptions are possible in rare cases.
Award Closeout Notices

KFS Team is working on the automated Award Closeout Notices for C&G

Proposed Process:

- Notices to be sent 60 days before the award stop date
- Notice recipients: PI (KFS-Award-Project Director) and all Fiscal Officers (KFS-Expense Account-Fiscal Officer)
Questions?

Contact: Beata Najman
Director, Extramural Funds Accounting
bnajman@uci.edu
(949) 824-0265
Agenda

• Announcements
• Industry Sponsored Research
• Contracts and Grants Accounting Update
• **Federal Update**
  • Research, Engagement and Facilitation (REF) Update
  • Clinical Trials Update
  • ClinicalTrials.gov/NIH Clinical Trial Definitions
  • Electronic Research Administration (ERA) Update
  • PI Exception Policy
  • Revisions to Proposal Submission Guidelines
• Data Warehouse
The only way to make sense out of change is to plunge into it, move with it, and join the dance.

–Alan Watts

Paul Lekutai
Supervising Principal Contract and Grant Officer
plekutai@uci.edu
(949) 824-4781

Erika Blossom
Supervising Principal Contract and Grant Officer
Erika.Blossom@uci.edu
(949) 824-2237
Staff Changes

• Lauren Nguyen, Federal Contract & Grant Officer
  – (949) 824-3171
  – Insoto@uci.edu

• Shelley Scallan, Senior Contract & Grant Officer
  – (949) 824-2644
  – sscallan@uci.edu

• Officer Assignments
NIH

• NIH Research Performance Progress Reports (RPPR)
  – Annual RPPR
    • Use to describe a grant’s scientific progress, identify significant changes, report on personnel, and describe plans for the subsequent budget period or year.
  – Final RPPR (replaced FPR)
    • Use as part of the grant closeout process to submit project outcomes in addition to the information submitted on the annual RPPR, except budget and plans for the upcoming year.
  – Interim RPPR
    • Use when submitting a renewal (Type 2) application. If the Type 2 is not funded, the Interim RPPR will serve as the Final RPPR for the project. If the Type 2 is funded, the Interim RPPR will serve as the annual RPPR for the final year of the previous competitive segment. The data elements collected on the Interim RPPR are the same as for the Final RPPR, including project outcomes.
# NIH

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Status of Competing Renewal Application</th>
<th>Workflow Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Competing Renewal not submitted</td>
<td>Submit a Final-RPPR no later than 120 calendar days from the period of performance end date.</td>
</tr>
<tr>
<td>2</td>
<td>Competing Renewal submitted</td>
<td>Submit an Interim-RPPR no later than 120 calendar days from the period of performance end date. If the competing renewal is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.</td>
</tr>
<tr>
<td>3</td>
<td>Competing Renewal submitted but not funded</td>
<td>Submit an Interim-RPPR no later than 120 calendar days from the period of performance end date. If the competing renewal is not funded, NIH will treat the Interim-RPPR as the institution's Final-RPPR. To reduce burden NIH will not require recipients to submit an additional Final-RPPR if the renewal application is not funded.</td>
</tr>
</tbody>
</table>
NIH

• **August 30: NIH Webinar on Research Performance Progress Reports (RPPRs)**

  – Registration was full, but;

  – A recording and transcript will be available approximately 5-7 business days following the event on the [NIH Grants YouTube channel](https://www.youtube.com).

  • We will notify you once the link is available.
NIH Policies for Clinical Trials

- Requires that all applications involving one or more clinical trials be submitted in response to a clinical trial-specific FOA. – Effective for receipt dates on or after January 25, 2018

- Expects all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials be trained in Good Clinical Practice (GCP). – Effective as of January 1, 2017

- Expects all NIH-funded clinical trials are registered and that results are submitted to ClinicalTrials.gov whether or not subject to FDAAA. – Applies to grants, contracts, and intramural clinical trials submitted on or after January 18, 2017
NIH

- New Application Packages (FORMS-E)
  - Required for Due Dates on or after January 25, 2018
  - Includes new Human subjects and Clinical Trial form
  - FORMS-E will be available October 2017
NIH - Reminder

- **Automated Post Award Changes**
  - Effective March 2, 2017, recipients of NIH awards can submit the following prior approval requests electronically through eRA Commons.
    - Prior Approval Request for Change of PD/PI
    - Prior Approval Request for No Cost Extension (NCE) (in addition to the requests made under expanded authority)
**Proposed Revision to Proposal & Award Policies & Procedures Guide (PAPPG) (Effective January 2018)**

- **New subcategory Institutions of Higher Education (IHE) for eligibility requirements.** Special instructions have been added for international branch campuses of IHEs. This would only impact us if we plan to issue a subaward to an international branch of a U.S. IHE.

- **Foreign organization eligibility as a subaward**
  - Contributes a unique organization, facilities, geographic location and/or access to unique data resources not generally available to U.S. investigators
  - The organization to be supported offers significant scientific and engineering education, training or research opportunities to the U.S.
Collaborators and Other Affiliations (COA)
- This spring NSF began piloting use of a spreadsheet template for submission of COA information
- The template will become required with the issuance of the new PAPPG in January 2018
- Additional information may be found on page 4 of the NSF’s Proposal & Award Policy Newsletter

- New Single Copy Document required for PIs that were Former NSF Staff
- New Section Header for “Intellectual Merit” will be required
- Results from Prior NSF Support required for any PI or Co-PI who has received NSF support with an end date within the past five years or an end date in the future
Vertebrate Animals
- Additional award condition stating it is the grantee’s responsibility to ensure that the Institutional Animal Care and Use Committee (IACUC) approval remains valid at all times that animal work is conducted under the award. Additional IACUC approval must be obtained if the protocols have changed substantively from those originally proposed and approved.

Human Subjects
- Now eight (8) categories of research that qualify for exemption to IRB approval
- New award-specific condition that it is the organization’s responsibility to ensure that an IRB approval for human subjects work remains valid at all times that such work is being conducted.
- Supplemental funding does not require a separate IRB approval letter unless the scope of the project has substantively changed.
Faculty Salary Policy – The Two Month Rule Clarification

- NSF’s compensation policy states that compensation for senior project personnel is generally limited to “no more than two months of their regular salary in any one year. This limit includes salary compensation received from all NSF-funded grants... If anticipated, any compensation for such personnel in excess of two months must be disclosed in the proposal budget, justified in the budget justification, and must be specifically approved by NSF in the award notice budget.”
- NSF has granted Awardees the authorization to transfer funds from one budget category to another for allowable expenditures including funds for faculty salary above the two month maximum. No prior approval from NSF is necessary for this type of rebudgeting unless the objectives or the scope of the project change.
- This policy applies to all senior personnel listed on the NSF budget, not just faculty on academic appointments.
- It is also acceptable for senior personnel to commit time and resources to a project without requesting salary. This should be documented in the Facilities, Equipment and Other Resources section of the proposal. That description should be narrative in nature and must not include quantifiable financial information.
• **Participant Support Costs Clarifications**
  - **Definition:**
    - Direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with NSF-sponsored conferences or training projects. Any additional categories of participant support costs other than those described in 2 CFR § 200.75 (such as incentives, gifts, souvenirs, t-shirts and memorabilia), must be justified in the budget justification, and such costs will be closely scrutinized by NSF. (See Chapter II.E.7).
  - The role of the student on the project must be used to determine how the student is compensated. A student cannot be compensated partially as an employee and as a participant unless they have separate and distinct roles (i.e. work on project academic year doing office work, participant during summer research program)
  - Participant Support Costs should be used to defray the costs of students participating in a conference or training activity related to the project.
  - Speakers who are being paid to speak/present at a conference **ARE NOT** considered participants. They should be included as other direct costs/consultants.
  - Prior approval is required to rebudget OUT of Participant Support Costs. Prior approval is not required to rebudget INTO Participant Support Costs, except if you are rebudgeting into the "Participant Support Costs - Other" category. NSF closely reviews costs that are listed in the "Participant Support Costs – Other" category. Be sure to clearly justify these costs
- Subsistence Costs
  - Subsistence Cost Category under Participant Support should only be used if funds will be paid directly to the participants for meals.
  - Participant Support Costs - Other Category should be used if funds will go directly to a service provider to aggregately pay for the cost of meals for participants only. This category will be highly scrutinized by NSF.
  - Other Direct Costs Category (Non-Participant support) should be used if funds will go directly to a service provider for room and food for participants and other attendees. Other attendees must be allowable in accordance with relevant UC/UCI policies. Because NSF policy does not normally allow for food expenses, these costs must be included in the proposal budget and fully justified in the budget justification. Food expenses that are not included in the proposal budget and justification are unallowable on an NSF grant.
Research Terms and Conditions (RTC) Reminder

RTC Agency Implementation Statements can be found at https://www.nsf.gov/awards/managing/rtc.jsp as well as agency specific Requirements for agencies that implemented the RTC.

Also available on the website are:

- Research Terms and Conditions Appendix A Prior Approval Matrix - June 30, 2017
- Research Terms and Conditions Appendix B Subaward Requirements - June 30, 2017
- Research Terms and Conditions Appendix C National Policy Requirements - May 23, 2017
QUESTIONS?
Agenda

- Announcements
- Industry Sponsored Research
- Contracts and Grants Accounting Update
- Federal Update
- **Research, Engagement and Facilitation (REF) Update**
  - Clinical Trials Update
  - ClinicalTrials.gov/NIH Clinical Trial Definitions
  - Electronic Research Administration (ERA) Update
  - PI Exception Policy
  - Revisions to Proposal Submission Guidelines
- Data Warehouse
Research Engagement & Facilitation (REF) Update

Nadia Wong
COI Administrator
nadiaw@uci.edu
August 30, 2017
New Form 800SR

• Combines the COI disclosure and training for non-UCI investigators and subrecipients following the institution's COI policy on PHS compliant projects.

• Implementation of this new form will take effect on August 31, 2017.

• Start using this form now! If not, we may require a new form be submitted if after the implementation date.

http://research.uci.edu/forms/docs/coi/PHS-Disclosure-Subrecipient-Form-800SR.doc
When will we request a new Form 800SR?

Proposal Stage
- If the creation date of the proposal is BEFORE 8/31, we will accept an old form.
- If creation date of the proposal is after 8/31 and old form is uploaded, we will request a new form.

Continuation Stage
- If any subrecipient is following our policy or non-UCI investigator is on the project, forms will need to be uploaded to the Personnel Doc. If old form is uploaded, we will request a new form.
Joint 700U/IRB Proposals

Must have all of the following:
• Non-governmental sponsor (check exempt sponsor list for exceptions)
• Sponsor made decision to fund the project at proposal stage
• New proposal is linked to a new IRB application

Goal: Combine the conflict of interest review for non-governmental sponsored proposals that have been awarded and have a new IRB application
Joint 700U/IRB Proposals

Changes:

• Form 700U for Joint 700U/IRB Proposals collected with New IRB Application (no longer uploaded in KC)
• Updated KC Questions
• Updated questions in New IRB Applications
• Updated Non-governmental Sponsor webpage: http://research.uci.edu/ref/conflict-of-interest/research-disclosures/non-gov.html
Form 700U Collection

- Standard Proposal
- After the Fact Proposal
  - Ex. Award transfers from another institution to UCI
- Joint 700U/IRB Proposal
  - Ex. Industry clinical trials

Each green question reflects an updated KC Proposal and/or the New IRB Application Question

Q1. Is the sponsor/prime sponsor a non-governmental entity (such as a for-profit or non-profit entity)?
  - Yes
  - No

Q2. Is that sponsor/prime sponsor on the exempt sponsor list?
  - Yes
  - No

Q3. Has the sponsor/prime sponsor made a decision to fund this project?
  - Yes
  - No

Q4. Is a New IRB Approval required before beginning work on this project?
  - No
  - Yes

Form 700U Reminders:
- Electronic copies of Form 700U must have handwritten signature
- Principal Investigators are responsible for submitting the original, wet-ink signed Form 700U to COI Team, Zot Code: 7600 for record-keeping
Implementation Date: September 25

• Newly created proposals: KC Proposal will automatically include the new KC Questions

• In progress proposals: Officers will instruct researchers to update their Questions in KC to transition to the new process
In-Progress Proposals

To update the KC Questions, go to the Questions tab, expand the panel, and click the “update” button. The default setting will retain your original answers.
In-Progress Proposals

In the default setting, you only have to respond to the new questions.
Helpful Tips

• Create and save the KC proposal before the New IRB Application for a Joint 700U/IRB Proposal to generate the proposal number.
  – The proposal number will be requested in your New IRB Application.

• To maximize the parallel processes, minimize the time between KC and New IRB Application submissions for a project if possible.
Http://research.uci.edu/ref/conflict-of-interest/index.html
PI Assistant (PHS Compliant Projects)

- PI Assistant role must be approved in KSAMS before the Personnel Doc is generated in order for the Department Administrator to have access to the Personnel Doc.
- PI Quickstart Guide- [http://research.uci.edu/ref/conflict-of-interest/forms-references/PrincipalInvestigatorQS.pdf](http://research.uci.edu/ref/conflict-of-interest/forms-references/PrincipalInvestigatorQS.pdf)
Any questions?

Nadia Wong
COI Administrator
nadiaw@uci.edu
Agenda

• Announcements
• Industry Sponsored Research
• Contracts and Grants Accounting Update
• Federal Update
• Research, Engagement and Facilitation (REF) Update
• **Clinical Trials Update**
  • ClinicalTrials.gov/NIH Clinical Trial Definitions
  • Electronic Research Administration (ERA) Update
  • PI Exception Policy
  • Revisions to Proposal Submission Guidelines
• Data Warehouse
Industry Clinical Trials Update

August 30, 2017
Industry Clinical Trials Team

Tam K. Tran  
Assistant Director  
tamkt@uci.edu  
949-824-7813

Shabana Durrani  
Principal Contract Officer  
durranis@uci.edu  
949-824-7697  
• All CDAs, non-master CTAs except for Depts. of Neurology, Dermatology, Pediatrics, IMIND

Heather Kubinec  
Principal Contract Officer  
hkubinec@uci.edu  
949-824-9816  
• All amendments, all master CTAs, all CTAs for Depts. of Neurology, Dermatology, Pediatrics, IMIND

Minimum Required Documents

• To begin the review and negotiation of a clinical trial agreement (CTA), we require the following to be provided in Kuali Coeus (KC):
  – KC document initiated and all required CT data elements complete
  – PI eligibility exception request, if required
  – 700U conflict of interest (COI) disclosure form (no longer required after 9/25/17)
  – Draft budget
  – Protocol
  – Draft agreement

http://research.uci.edu/sponsored-projects/clinical-trials/starting-point.html
Joint IRB/COI Review Implementation

• 700U form is no longer submitted in KC as part of the proposal minimum required documents after 9/25/17. The 700U form will be submitted with the IRB application to streamline COI review.

• Tips:
  – Create and save KC proposal before the new IRB application to generate a proposal number. Include the proposal number in new IRB application.
  – Update COI questions in KC
    • Proposals generated prior to 9/25/17 will include the “old” COI questions.
KC Clinical Trial Negotiation Module

- Tracks status of all CDAs, CTAs, contract modifications, and other CT-related agreements
- Indicates officer assigned
- Shows status of other regulatory approvals such as COI, IRB and KC (budget and coverage analysis)
- Full implementation July 2017
- We welcome your feedback and comments!
### Principal Investigator/Department View

#### Regulatory Status and Approval Dates

<table>
<thead>
<tr>
<th>Regulatory Status</th>
<th>Approval Dates*</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB:</td>
<td>01/13/2017</td>
<td></td>
</tr>
<tr>
<td>COI:</td>
<td>11/08/2016</td>
<td></td>
</tr>
<tr>
<td>Approved KC Document Received by SPA:</td>
<td>04/14/2017</td>
<td></td>
</tr>
</tbody>
</table>

*Approval in this instance means it has been cleared.

#### Project Status Timeline

<table>
<thead>
<tr>
<th>Status</th>
<th>Activity Start Date</th>
<th>Activity End Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Award Finalized in SPA Database &amp; Synopsis Released</td>
<td>04/28/2017</td>
<td>04/28/2017</td>
<td></td>
</tr>
<tr>
<td>Processed and Released to Accounting</td>
<td>04/27/2017</td>
<td>04/27/2017</td>
<td></td>
</tr>
<tr>
<td>Received Fully Executed Agreement from Sponsor</td>
<td>04/25/2017</td>
<td>04/26/2017</td>
<td></td>
</tr>
<tr>
<td>Sent Partially Executed Agreement to Sponsor/CRO</td>
<td>04/26/2017</td>
<td>04/26/2017</td>
<td></td>
</tr>
<tr>
<td>Contract to PI for Signature</td>
<td>04/19/2017</td>
<td>04/19/2017</td>
<td></td>
</tr>
<tr>
<td>Received Final Agreement</td>
<td>04/18/2017</td>
<td>04/18/2017</td>
<td></td>
</tr>
<tr>
<td>Contract Terms Finalized (Excludes Budget &amp; Payment Terms)</td>
<td>04/10/2017</td>
<td>04/10/2017</td>
<td></td>
</tr>
<tr>
<td>Under Negotiation Between SPA and Sponsor/CRO</td>
<td>12/12/2016</td>
<td>04/10/2017</td>
<td></td>
</tr>
<tr>
<td>SPA Received Response from Sponsor/CRO</td>
<td>12/12/2016</td>
<td>12/12/2016</td>
<td></td>
</tr>
<tr>
<td>Initial Redlines Sent to Sponsor/CRO</td>
<td>12/02/2016</td>
<td>12/02/2016</td>
<td>Checked with sponsor/cro to use ACTA template; Sponsor want to use their CTA template</td>
</tr>
<tr>
<td>Notification to SPA</td>
<td>11/08/2016</td>
<td>11/08/2016</td>
<td></td>
</tr>
</tbody>
</table>
CLINICALTRIALS.GOV Registration

- Investigator initiated clinical trials that are required to be registered in clinicaltrials.gov
  - Award synopsis will include the clinicaltrials.gov registration notification
  - IMPORTANT REMINDER: This clinical trial requires the registration on a public database and website, www.clinicaltrials.gov within 21 days of the first subject enrollment. The Principal Investigator is the responsible party for ensuring this trial is registered, results are reported and that all errors are resolved. Additional information to help comply with this requirement may be found at http://www.research.uci.edu/compliance/human-research-protections/researchers/guidelines-for-registering-in-a-clinicaltrialsgov-registry.html
Questions?
Agenda

- Announcements
- Industry Sponsored Research
- Contracts and Grants Accounting Update
- Federal Update
- Research, Engagement and Facilitation (REF) Update
- Clinical Trials Update
- **ClinicalTrials.gov/NIH Clinical Trial Definitions**
- Electronic Research Administration (ERA) Update
- PI Exception Policy
- Revisions to Proposal Submission Guidelines
- Data Warehouse
CLINICAL TRIALS THAT REQUIRE REGISTRATION AT CLINICALTRIALS.GOV

Effective
January 18, 2017

NIH

DHHS

Laverne Estanol
Assistant Director, Human Research Protections
A research study\(^1\) in which one or more human subjects\(^2\) are prospectively assigned\(^3\) to one or more interventions\(^4\) (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.\(^5\)

\(^1\)See Common Rule definition of research at 45 CFR 46.102(d).

\(^2\)See Common Rule definition of human subject at 45 CFR 46.102(f).

\(^3\)The term “prospectively assigned” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

\(^4\)An intervention is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

\(^5\)Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Clinical Trial. For purposes of this policy, a “clinical trial” means “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” [3] This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g., behavioral interventions. This definition of “clinical trial” [4] is broader than the term “applicable clinical trial” as defined in the regulation. [5]
Decision Tree for NIH Clinical Trial Definition

Note: Not considered clinical trials:

- surveys,
- questionnaires,
- user preferences,
- focus groups,
- secondary research with biospecimens or health information.

**ALL** criteria below must be true to meet **NIH Policy** requirement:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH Funded</td>
<td>wholly or partially verification of the terms and conditions of the NIH award, which should indicate the study is identified as a <strong>clinical trial</strong>.</td>
</tr>
<tr>
<td>Initiated on or after January 18, 2017</td>
<td></td>
</tr>
<tr>
<td>Meets definition of <strong>Human Subjects Research</strong> [45 CFR 46.102(d) and 45 CFR 46.102(f)]</td>
<td></td>
</tr>
<tr>
<td>Protocol includes <strong>prospectively assigning</strong> research participants to one or more arms of an intervention</td>
<td></td>
</tr>
<tr>
<td>Protocol includes an <strong>intervention</strong> with an endpoint of modifying one or more health-related biomedical or behavioral processes</td>
<td></td>
</tr>
<tr>
<td><strong>Includes</strong> phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA (e.g., behavioral interventions)</td>
<td></td>
</tr>
<tr>
<td>Protocol includes a <strong>health-related biomedical or behavioral outcome</strong> endpoint(s) resulting from an intervention</td>
<td></td>
</tr>
</tbody>
</table>

### TOOLS / RESOURCES

- **NIH Online decision tree (yes/no questions)**

- **NIH FAQs (10) and Examples (6 scenarios)**

- **NIH 33 Case Studies (biomedical and behavioral)**

- **UCI HRP webpage:**
    - *guidance for responsible party, submission timelines, creating a profile on clinicaltrials.gov*

### RELATED NIH NOTICE

- NIH will require that all applications involving one or more clinical trials be submitted through a Funding Opportunity Announcement (FOA) specifically designed for clinical trials *(effective September 27, 2017)*
<table>
<thead>
<tr>
<th>ALLELIC DEVICE CLINICAL TRIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>The following elements are <strong>all</strong> required:</td>
</tr>
<tr>
<td>☐ Protocol includes <strong>human subjects</strong></td>
</tr>
<tr>
<td>☐ Protocol meets the definition of a <strong>clinical study</strong></td>
</tr>
<tr>
<td>☐ Protocol is prospective in nature</td>
</tr>
<tr>
<td>☐ Protocol includes ascertaining health <strong>outcomes</strong> as an endpoint</td>
</tr>
<tr>
<td>☐ Protocol <strong>compares</strong> an <strong>intervention</strong> with a device</td>
</tr>
<tr>
<td>☐ Protocol includes a <strong>control</strong> population</td>
</tr>
<tr>
<td>☐ Protocol includes a <strong>device</strong> product subject to FD&amp;C Act [21 U.S.C. 321(h)]</td>
</tr>
<tr>
<td>☐ Study occurs within the US (or US territory); or, the device is manufactured in the US (or US territory) and is exported for study in another country</td>
</tr>
<tr>
<td>☐ Protocol is <strong>not</strong> a feasibility study</td>
</tr>
</tbody>
</table>

**OR**

| ☐ Protocol is a **pediatric postmarket surveillance** of devices |

### Applicable Drug Clinical Trial

The following elements are **all** required:

- [ ] Protocol meets definition of a *controlled clinical investigation*
- [ ] Protocol is **not** a *Phase 1 trial*
- [ ] Protocol includes a drug ([Chapter II Section 201(q), page 4](https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission#p-1191)) (or biologic [42 USC 262(l)]) that is subject to [FD&C Act](https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission#p-1191) [has an IND, NDA or BLA]
  OR
  Protocol includes a drug (or biologic) that is **exempt from IND requirements**
- [ ] Study occurs within the US (or US territory); or, the drug is manufactured in the US (or US territory) and is exported for study in another country under an IND
**RESOURCE / TOOL**

**UCI HRP webpage:**

  - Guidance for responsible party, submission timelines, creating a profile on clinicaltrials.gov

  - Deeper dive into the definitions: pages 6-11
REGISTRATION AT CLINICALTRIALS.GOV

Registration Steps

1. Responsible Party (RP) will register at ClinicalTrials.gov: system will prompt questions to help determine whether a study is an ACT (applicable clinical trial)
2. PRS (ClinicalTrials.gov team) will review the registration information: 2-5 business days

3. PRS will provide comments to the RP: completion time depends on the comments and the response time from the RP and PRS [this is an opportunity to verify the study is an ACT or not]

* a registration record can only be deleted if it has not yet been assigned an NCT#

4. After review of comments are accepted, PRS will assign the registration record an NCT #: study will be posted publicly within 2 business days

5. After an NCT # has been assigned (regardless of ACT/non-ACT status), there are obligations for providing system updates; and there are obligations for providing results (results only for ACTs)

* Only the RP can approve/release transactions (i.e., register, update, results) in the system; a designated/assigned individual can prepare the transactions

Creating a profile on ClinicalTrials.gov

For research that meets one of the above definitions (see tables 1 and 2 above), and are conducted within a department at the School of Medicine, please contact Mark Bourbons (mbourbon@hs.uci.edu, 949-682-5440) to create a profile (record) on ClinicalTrials.gov.

For all other research that meets one of the above definitions (see tables 1 and 2 above), and are not conducted within a department at the School of Medicine, please contact Laverne Estañol (lestanol@uci.edu, 949-824-4704) to create a profile (record) on ClinicalTrials.gov.
Agenda

- Announcements
- Industry Sponsored Research
- Contracts and Grants Accounting Update
- Federal Update
- Research, Engagement and Facilitation (REF) Update
- Clinical Trials Update
- ClinicalTrials.gov/NIH Clinical Trial Definitions
- **Electronic Research Administration (ERA) Update**
- PI Exception Policy
- Revisions to Proposal Submission Guidelines
- Data Warehouse
We are ER(y)A(y)!!

• What we do…
  – Analysis, implementation, training, support, updates, upgrades, communication:
    • All systems, both internal and external, utilized in Research Administration
  – Coordination of Research Administration training and education
  – Data Integrity
Reminders

• SPA’s Central Award Inbox
  – awards@research.uci.edu

• SPA Departmental Assignment Tool
  – New “smart search” feature

http://www.research.uci.edu/sponsored-projects/about/staff-dept-assignment.html
KC Upgrade to KR

- On track to upgrade to KR June 2018
- User interface changes to Proposal Development only
- KC COI will continue operating with current interface
  - UCI is working with Kuali to further develop KR COI
- Going through code customizations
  - Looking for opportunities to streamline
  - We want to hear from you! Contact us with your KC streamlining ideas! era@research.uci.edu
Proposal: #722
PI: Not yet assigned

Proposal Details
* indicates required fields

Document was successfully saved.

Proposal Type: * New - Change/Corrected

Lead Unit: IN-CARD - CARDIOLOGY

Activity Type: * Research
<table>
<thead>
<tr>
<th>Key Personnel</th>
<th>Lead Unit: IN-CARD - CARDIOLOGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity Type:</td>
<td>Research</td>
</tr>
<tr>
<td>Project Dates:</td>
<td>12/01/2016 to 12/31/2016</td>
</tr>
<tr>
<td>Project Title:</td>
<td>This is the song that never ends</td>
</tr>
<tr>
<td>Sponsor:</td>
<td>004090</td>
</tr>
<tr>
<td>Prime Sponsor Code:</td>
<td></td>
</tr>
<tr>
<td>Award ID:</td>
<td></td>
</tr>
<tr>
<td>Original Institutional Proposal ID:</td>
<td></td>
</tr>
<tr>
<td>Keywords:</td>
<td>Nothing selected</td>
</tr>
</tbody>
</table>
KC Negotiations Module(s)

• The KC Negotiations module are maintained by Officers in Sponsored Projects Administration (SPA)
• Contains information on the various activities involved award setup.
• Provides transparency to Principal Investigators, Chairs, Deans, their support staff and managers into pending actions and who is responsible for completing them.
• Information available includes award receipt date, status of agreement review and negotiation, status of compliance review(s), and the dates and responsible party associated with each action.
KC Negotiations Module(s)

- Currently “soft launched”
- Two versions:
  - Federal and Non-Federal Team
  - Industry Clinical Trials Team
- Will announce broadly soon and post information on ERA website.
Zot!Portal -> Research tab -> Kuali Coues

Lookups:

- One status for each module for all records
- One status for each module for all records for the PI (person logged into Zot!Portal)
### KC Negotiations Module for Federal/Non-Federal

<table>
<thead>
<tr>
<th>Activity Title</th>
<th>PI/Department Admin</th>
<th>Responsible Party</th>
<th>Action to be Taken</th>
<th>Activity Start Date</th>
<th>Activity End Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>207346 Contract</td>
<td>GABY THAI</td>
<td>REPUBLIC OF SOUTHERN CALIFORNIA</td>
<td>Provide Additional Documentation/Information</td>
<td>01/31/2017</td>
<td></td>
<td>Requested PI to be included in Protocol</td>
</tr>
<tr>
<td>807060 Multiple Campus Subaward</td>
<td>SHELDON GREENFIELD</td>
<td>REPUBLIC OF UC SAN FRANCISCO</td>
<td>Award/Agreement Review</td>
<td>01/26/2017</td>
<td>01/31/2017</td>
<td>01/26/2017 - Award Received</td>
</tr>
</tbody>
</table>
KC Negotiations Module for Industry Clinical Trials

<table>
<thead>
<tr>
<th>Actions</th>
<th>Proposal #</th>
<th>Award Type</th>
<th>Action</th>
<th>Principal Investigator Name</th>
<th>Sponsor Name</th>
<th>Title</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>View</td>
<td>208673</td>
<td>Contract: Clinical Trial</td>
<td>New Award</td>
<td>SUMIT GARG</td>
<td>VISIONCARE OPHTHALMIC TECHNOLOGIES LTD.</td>
<td>A PROSPECTIVE, MULTICENTER CLINICAL TRIAL OF THE IMPLANTABLE MINIATURE...</td>
<td>TAN</td>
</tr>
<tr>
<td>View</td>
<td>208639</td>
<td>Contract: Clinical</td>
<td>New</td>
<td>MEHRANEH TAFARI</td>
<td>LEADING BIOSCIENCES, INC</td>
<td>A Randomized, Double-Blind, Placebo-Controlled, Proof of Concept Study</td>
<td>TAN</td>
</tr>
</tbody>
</table>

**SUMIT GARG | 208673 | VISIONCARE OPHTHALMIC TECHNOLOGIES LTD. | Contract: Clinical Trial | New Award**

<table>
<thead>
<tr>
<th>Regulatory Status</th>
<th>Approval Dates*</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB</td>
<td>07/14/2017</td>
<td></td>
</tr>
<tr>
<td>COI</td>
<td>05/09/2017</td>
<td></td>
</tr>
<tr>
<td>Approved KC Document Received by SPA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Approval in this instance means it has been cleared.

<table>
<thead>
<tr>
<th>Status</th>
<th>Activity Start Date</th>
<th>Activity End Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under Negotiation Between SPA and Sponsor/CRO</td>
<td>05/22/2017</td>
<td></td>
<td>SPANegotiation: Sponsor's changes have been incorporated</td>
</tr>
<tr>
<td>SPA Received Response from Sponsor/CRO</td>
<td>05/22/2017</td>
<td>05/22/2017</td>
<td>Sponsor agreed to use ACTA with changes</td>
</tr>
<tr>
<td>Initial Redlines Sent to Sponsor/CRO</td>
<td>05/09/2017</td>
<td>05/09/2017</td>
<td>Sent ACTA to sponsor for review.</td>
</tr>
<tr>
<td>Notification to SPA</td>
<td>05/01/2017</td>
<td>05/01/2017</td>
<td></td>
</tr>
</tbody>
</table>
RMS – IACUC Protocol Form Revisions

NEW & IMPROVED!
Animal-use Protocol Form in RMS
IACUC Protocol Form Revisions

• Streamlined the form questionnaires to make it easier to use and follow
• Reduced the number of tabs & sections to complete
• Made improvements to the user interface
• Revised the help text with better explanations, links to instructions and visuals
Streamlined the form questionnaires

### Study Characteristics

- Indicate if any of the following will be performed, applied, or used in live animals for this protocol - Check all that apply:
  - Teaching Protocol (used for training purposes)
  - Field Studies
  - Surgery
  - Breeding
  - Prolonged Restraint (without sedation or anesthesia)
  - Paralytic Agents
  - Antibody Production

#### Updated/Added Parent-Child list questionnaires

Clicking on the Parent item, expands with additional questions

### Types of Surgery

- Check all that apply:
  - Terminal = Animal is euthanized without regaining consciousness
  - Survival = Animal is recovered from anesthesia and kept alive for a period after the surgery, where post-up care/monitoring is provided
  - Major = Any surgical procedure that penetrates or exposes a body cavity or result in permanent impairment of normal physical or physiological functions
  - Minor = Does not penetrate/expose body cavity nor result in permanent impairment. (Examples: Laporoscopy, superficial vascular cutdown, percutaneous biopsy, etc.)

See the [IACUC Policy on Surgery](#) for more information.

- Terminal (animals will not recover from anesthesia)
- Survival
Streamlined the form questionnaires

Pre-populated tables embedded in forms

Removed redundant/repeated questions in forms.
Reduced the number of tabs/sections

**Before**
- General Information
- Teaching Protocol
- Field Studies
- Personnel
- General Training
- Species
- Rationale/Alternatives
- Study Segments
  - Animal Numbers
  - Procedures
  - Procedures Training Verification
  - Drugs and Other Agents
  - Animal Monitoring & Other Info
  - Protocol/Forms Links
  - Animal Husbandry/Housing
  - Safety & Hazards
  - PI Certification

**After**
- General Information
- Species
- Rationale & Alternatives
- Experimental Design
- Animal Numbers
- Procedures
- Drugs & Agents
- Animal Locations & Husbandry
- Hazards & Safety
- Other Information
- Personnel
- Training Requirements
- Links to Other Protocols
- PI Certification

- Combined teaching and field study tabs into the general info tab
- Removed the Procedures Training Verification based on user feedback
- Reorganized the protocol submission layout to closely match the previous Word Document form
Made improvements to the user interface

- Removed frequently used action items from Action Menu for easier access
- Increased font size of header sections for better visibility
Revised help text

Button links to online user guide

Clearer step by step instructions with better visuals and links
Questions? Comments? Feedback?

Contact rms-support@uci.edu or call (949) 824-2142
Adobe PDF Application Packages

- Will be retired December 31, 2017
  - No longer able to download PDF application forms
- Grace period: if you download a PDF package before 12/31/17, it can still be submitted through March 31, 2018
- Replaced with a New Online Application Tool
Grants.gov Workspace

• Online completion and submission of application forms
• PIs & Admins must register for a Grants.gov account under UCI’s Organizational Account using our DUNS number
• Another system to learn and adapt to…

**No effect on you if you’re using Cayuse 424!**
# Grants.gov Workspace vs. Cayuse 424

<table>
<thead>
<tr>
<th>Functionality</th>
<th>Workspace</th>
<th>Cayuse 424</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supports Grants.gov Applications</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>NSF FastLane Support</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Up to date forms &amp; validations</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Maintain a complete repository &amp; history of proposals</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Individual Forms Validation</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Copying a Proposal</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Access to Edit Proposal by Non-UCI Collaborators</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Downloadable Forms for Offline Completion</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Form reuse feature</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Real-Time Error Checking</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Auto-population of Institutional Data</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Auto-population of Personal Profile Data</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Transforming a Proposal from one RFA to another</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Upload and store multiple biosketches</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Budget building capability</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>
Grants.gov Workspace

• Overview & training of system will be available at ERA Office Hours (next session: Sept. 12; register on UCLC)

*4 out of 5 Research Administrators recommend Cayuse 424 as their preferred system to use*
ERA team is here to help!
Contact Us (before it’s too late)

era@research.uci.edu

Join us for ERA Office Hours:
Register in UCLC
Training available in Public Access Compliance, Kuali Coeus, Grants.gov Workspace and more.
Next ERA Office Hours: September 12, 2017
Agenda

• Announcements
• Industry Sponsored Research
• Contracts and Grants Accounting Update
• Federal Update
• Research, Engagement and Facilitation (REF) Update
• Clinical Trials Update ClinicalTrials.gov/NIH Clinical Trial Definitions
• Electronic Research Administration (ERA) Update
• **PI Exception Policy**
• Revisions to Proposal Submission Guidelines
• Data Warehouse
Sponsored Projects Process Updates

• PI Exception Approvals
  – PI Exceptions policy updated to delegate approvals to the Deans for school-based exception requests
    • Approvals are transmitted to SPA or ISR in KC with the proposal
    • SPA Management logs the approval in the SPA database
  – PI Exception approvals for ORU’s remain with the Vice Chancellor for Research (VCR)
    • Exception requests are submitted to SPA or ISR via KC
    • SPA Management facilitates review by the VCR or VCR’s desiginee
Agenda

• Announcements
• Industry Sponsored Research
• Contracts and Grants Accounting Update
• Federal Update
• Research, Engagement and Facilitation (REF) Update
• Clinical Trials Update ClinicalTrials.gov/NIH Clinical Trial Definitions
• Electronic Research Administration (ERA) Update
• PI Exception Policy
• Revisions to Proposal Submission Guidelines
• Data Warehouse
Revisions to Proposal Submission Guidelines

- Late Proposal Approval Request Form is no longer required
- Late proposal notification should be submitted to the vcrlateproposal@uci.edu e-mail address
- Federal and Non Federal team supervisors will review and respond to the notifications
- Notifications may be sent by the PI or Administrator
- Proposal Submission Guidelines are being revised to reflect this new procedure
Agenda

• Announcements
• Industry Sponsored Research
• Contracts and Grants Accounting Update
• Federal Update
• Research, Engagement and Facilitation (REF) Update
• Clinical Trials Update ClinicalTrials.gov/NIH Clinical Trial Definitions
• Electronic Research Administration (ERA) Update
• PI Exception Policy
• Revisions to Proposal Submission Guidelines

• **Data Warehouse**
## Composite Fringe Benefit Rates

**Effective October 1, 2017**

<table>
<thead>
<tr>
<th>Retirement Eligible</th>
<th>FY 2017-18 Rate</th>
<th>FY 2018-19 Rate</th>
<th>FY 2019-20 Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>32.8%</td>
<td>33.3%</td>
<td>33.7%</td>
</tr>
<tr>
<td>C</td>
<td>37.7%</td>
<td>38.4%</td>
<td>38.8%</td>
</tr>
<tr>
<td>D</td>
<td>49.5%</td>
<td>50.7%</td>
<td>51.5%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-Retirement Eligible</th>
<th>FY 2017-18 Rate</th>
<th>FY 2018-19 Rate</th>
<th>FY 2019-20 Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>E Postdoc Employees</td>
<td>24.1%</td>
<td>25.2%</td>
<td>26.3%</td>
</tr>
<tr>
<td>F Grad &amp; Undergrad Students</td>
<td>1.3%</td>
<td>1.3%</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

*Projected rates are for budgeting purposes only. The rate structure will be changing with the conversion to UC Path.*
Campus Data Warehouse

- datawarehouse.uci.edu Sponsored Projects ad-hoc query
- Using some parameters may result in incomplete data sets
- Parameters affected:
  - **Proposal Tab**
    - Proposal Sponsor Category Code*
    - Proposal Sponsor Category Description*
    - Proposal F&A Cost
    - Proposal F&A Rate
    - Proposal F&A Base Code
    - Proposal F&A Base Description
  - **Award F&A Cost Info Tab**
    - Award F&A Base Code
    - Award F&A Base Description
    - Award F&A Rate
  - **Award Tab**
    - Award Sponsor Category Code*
    - Award Sponsor Category Description*
    - Award F&A Cost

*Sponsor category codes will be fixed with the KC/SPA monthly deployment scheduled for 09/06/2017

*In the meantime, for assistance with SPA related data, please contact [era@research.uci.edu](mailto:era@research.uci.edu)*
Thank you...

…to all of you for reporting inconsistencies with your queries! It has helped ERA and OIT work towards identifying and resolving the issues.
Any final questions or comments?
See you next time...

Fall/Winter QRAM
• Date: Wednesday, December 6
• Time: 1:30-3:30
• Location: UCI Student Center – Moss Cove B