Quality Research Administration Meeting

March 29, 2017
Participate in today’s polls!

Join by:

Text: JONATHANLEW334 to 37607

or go to:

Pollev.com/jonathanlew334
Agenda

• General Announcements
• Grants Management Group
• Research Engagement and Facilitation Update
• ERA Update
• Federal Update
• Subrecipient Monitoring: Best Practices
• Industry Clinical Trials Update
• Human Research Protections Update
• Contracts and Grants Accounting Update
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
  – Public Access Compliance
  – KC Conflict of Interest
  – Coming soon…Subrecipient Monitoring

• Subscribe Today!
Start thinking now...

- We will conduct a survey at the end of today’s QRAM
- What topic(s) would you like to see on the OR YouTube channel?
- Do you have a FAQ that you would like to see answered?
- Is there a common problem that you encounter where a short video might help?
Agenda

- General Announcements
- **Grants Management Group**
- Research Engagement and Facilitation Update
- ERA Update
- Federal Update
- Subrecipient Monitoring: Best Practices
- Industry Clinical Trials Update
- Human Research Protections Update
- Contracts and Grants Accounting Update
Grants Management Working Group

Nancy Lewis
Executive Director, Sponsored Projects Administration
Membership

• Bruce Morgan
  – Associate Vice Chancellor for Research Administration

• Nancy Lewis
  – Executive Director, Sponsored Projects Administration

• Eric Taggart
  – Associate Director, Enterprise Applications

• Beata Najman
  – Director, Extramural Funds Accounting

• Marc Guerra
  – Controller

• Patrick Dutcher
  – Communications Officer, Accounting
Mission

To promote and facilitate the coordinated development and dissemination of (including communication about) faculty-centric, self-help oriented tools and highly-efficient, streamlined processes for the benefit of all grants management stakeholders.
Charge

In January 2017, the Grants Management Workgroup (GMW) was collectively charged by the Provost, the Vice Chancellor for Research and the Chief Information Officer to act as a coordinating body for the creation, dissemination and communication of faculty-centric, self-help oriented grants management tools and highly-efficient, streamlined processes.

The charge includes ensuring:

• That current and future tools and processes minimize burden and maximize efficiency for all stakeholders for balancing risk;
• The coordinated sharing plans between OR, A&FS and OIT;
• That communications (and presentations) are consistent and well-integrated regardless of the lead office;
• That tools are easily accessible and that tool access is customizable;
• That CORCL is used as an advisory group to help inform GMW efforts, activities, projects and products;
• The development, launch and on-going support of a faculty-centric e-mail publication that conveys important information about tools, processes and new developments; and
• The development, delivery and on-going support of outreach activities to faculty and their support staff.
Questions?
Agenda

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Research Engagement & Facilitation (REF) Updates

Spring 2017 QRAM
Research Engagement & Facilitation

• Goal: Encourage research compliance through problem-solving and outreach

• Team:
  – Marci Copeland (Export Control Officer)
  – Nadia Wong (COI Administrator)
  – Amy Green (COI Analyst/DURC Administrator)
We want to hear from you!

We are looking for:

• Suggestions and feedback
• In-person opportunities, like meetings, to create awareness and engage the campus
• Ideas on how to better communicate with campus
Conflict of Interest Updates

Nadia Wong
COI Administrator
700U Clarification

• COI staff conducts review based on scanned copies of the Form 700U with handwritten signatures to expedite the process
  – Officers have been instructed to request a revised Form 700U if they receive a typed signature or an electronic signature

• It is the faculty member’s responsibility to send the original, wet-ink signed Form 700U to the Office of Research (Attn: COI, Zot Code: 7600) to satisfy the California State Law requirements
COI Follow-Up

• To facilitate the COI review process, COI staff started copying administrative contacts to emails requesting COI forms and revisions
  – Please help us collect these forms and forward the email to the appropriate person if necessary
• COI staff is also sending follow-up emails after 2 weeks if we have not received the forms or revisions
• One main cause for a prolonged COI review is when we do not receive the forms in a timely manner
Updated Startup Guide for Employee Inventors

• Easier to read
• Features other faculty members who have created companies
• Highlights additional campus resources

Available at: http://innovation.uci.edu/wp-content/uploads/2017/02/1004.05-Startup_Guide.pdf
Future COI Developments

• Next phase of KC COI
• New streamlined Industry Supported Clinical Research process to allow one combined COI review for these projects- Working with Industry Sponsored Research, Clinical Trials, IRB, and ERA
• Interactive online version of the Startup Guide
Export Control Updates

Marci Copeland
Export Control Officer
RFP’s that indicate ITAR subject

- Increase in RFPs that indicate the research subject is ITAR for proposals we are submitting as a subcontractor
- Route these to Export Control right away for consultation
  - EC will advise PI on structuring the proposal scope of work to show clear separation between UCI’s fundamental research portion and sponsor’s restricted portion.

TECHNOLOGY AREA(S): Materials/Processes

The technology within this topic is restricted under the International Traffic in Arms Regulation (ITAR), which controls the export and import of defense-related material and services. Offerors must disclose any proposed use of foreign nationals, their country of origin, and what tasks each would accomplish in the statement of work in accordance with section 5.4.c.(8) of the Announcement.
Export Control Resources

Intro to Export Controls: 6 minutes
Traveling abroad: 4 minutes
ITAR: 7 minutes
Biological Agents: 5 minutes
OFAC: 3 minutes
International Shipping Overview: 6 minutes
International Shipping Documentation: 11 minutes

Google – UCI/Export Control
Export Control Resources

International shipping and hand-carrying – legal requirements

International Shipping and Hand-Carrying

To help ensure that UC faculty, staff, and students do not experience customs delays, seizure of goods, or inadvertent violation of federal export laws the below describes the basic requirements for international shipping and hand carry of items abroad. Incorrect shipping paperwork can lead to delays in shipments, lost time and lost opportunity. Failure to obtain an export license when required could result in fines of $250,000 to $1 million per violation and prison time for criminal convictions. False export declarations fines are $10,000. Customs fines vary by country and can also include seizure or detention of goods. Before shipping internationally, contact the Office of Research, Export Control Officer at m.copeland@uci.edu for assistance in determining whether an export license is required, securing a license when needed, and advice on what records need to be maintained in cases where the item can be
Questions or Comments?
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Electronic Research Administration (ERA) Update

Barbara Inderwiesche, Assistant Director
Jonathan Lew, ERA Officer
Martin Nakatsu, Sr ERA Analyst
RMS – Phase 2 Animal Ordering Update

Martin Nakatsu
Animal Ordering Module

- Released on Feb. 1st
- RMS replaces the old ULAR request form
- Direct RMS-KFS integration
- Complete tracking of the animal order in RMS
- Over 1000 animal orders have been placed with the new system
End-user Opinions

• User acceptance was less than enthusiastic
• A major issue was restricting an animal purchase to a single default KFS Account # per order
• Split funding for purchasing
• Multiple-line items in RMS
End-user Opinions

- User acceptance was less than enthusiastic
- A major issue was restricting an animal purchase to a single default KFS Account # per order
- Split funding for purchasing
- Multiple-line items in RMS
RMS Phase 2 Updates/Info

- Multiple KFS accounts for animal procurement are now available!

Billing

The RMS Shell Account Number is a combination of the selected AUP # linked to a KFS Account #.

_**UPDATE:**_ An AUP can NOW be linked to MULTIPLE KFS Account Numbers.

For detailed instructions, click [HERE](#).

Please contact Soo Lee: [sooyl@uci.edu](mailto:sooyl@uci.edu) if you need to link a new KFS Account Number to an AUP for an

- Account number*: [INVESTIGATOR,P/AUP-17-09/FG12345 (Federal Grant)]
- PO# (ULAR Use Only):
  - [INVESTIGATOR,P/AUP-17-09/FG12345 (Federal Grant)]
  - [INVESTIGATOR,P/AUP-17-09/FG12345-50/FG5321-50 (Split Funding)]
  - [INVESTIGATOR,P/AUP-17-09/FG54321 (Federal Grant)]
  - [INVESTIGATOR,P/AUP-17-09/PC02468 (Private Contract)]

Standing Order Request
RMS Phase 2 Updates/Info

- Split funding for animal purchases will also be available soon
RMS Phase 2 Updates/Info

- Multiple-line items
RMS Phase 2 Updates/Info

• Financial Accounting Units (FAUs) in RMS
  – Currently, only the Account number and Object code are collected, validated and passed through KFS.
  – We are currently working on integrating these accounting units into RMS and the list will include: Project codes, Sub Account, Sub Object
RMS Phase 2 New Feature

- Added a pop-up contact window for users in the request module
RMS Phase 2 New Feature

- Users can check their contact info from the pop-up window and update their profile
Questions? Comments?

Martin Nakatsu: mnakatsu@uci.edu or rms-support@uci.edu
(949) 824-2142
SPA Database Update

• Email to department contact when SPA sets up award
• Text:
  ...to C&G Accounting (cgaccounting@uci.edu), and include the necessary information in the spaces provided below:
  UC Account Number:
  Organization Code (lowest Org Code):
  KFS Account for the continuation account:
  Fiscal Officer (UCInetID):
  Account Supervisor (UCInetID):
  Account Manager (PI UCInetID):
  If cost sharing is required, provide the unrestricted KFS Account where the cost share expenses need to be charged:
• ERA is working with the database team on the implementation
• Likely in May 2017 monthly deployment
What’s new with KC?

KC to SPA Proposal Data Transfer Process:

1. Proposal Development Document:
   - routed for review and approval

2. SPA submits proposal to sponsor & enters submit date/time on IR Panel in KC

3. Overnight data transfer: KC to SPA Database
   - SPA Proposal Status = "Proposal Pending Review"

4. SPA finalizes proposal in KC and clicks "Approve" and "Submit to Sponsor"

5. Overnight data update: KC to SPA Database
   - SPA Status = Proposal Pending Award**

6. KC Proposal # is SPA Proposal # and is available in Data Warehouse
What’s new with KC?

- Special Review Tab: allow new protocol number format for IACUC protocols created in RMS. (AUP-12-34)

- Expand character limitation for return notes from 2000 to 4000. This refers to the review notes from the SPA Officers that are displayed in the Route Log.

- Updated CT Questions

- **Remember:** Update Questionnaires!
What’s new with KC?

• **NEW:** Abstracts and Attachments Tab: Notes
  – 4000 character free text field for use by anyone who has the proposal in their node.
  – Be advised: notes become part of the record and are visible by anyone who has access to view the proposal.
  – Give the note a topic, enter the text and click “add”. The note is timestamped and documents the Author.
ERA Support

• The ERA Team is prepared to provide support

• ERA Team:
  – Barbara Inderwiesche, Jonathan Lew, Alison Yeung, Kim Frazer and Martin Nakatsu

• Send email to era@research.uci.edu
KC-project list serv

- KC-Project OR-ERA

- We will migrate all KC-Project Subscribers to OR-ERA

- Timeline: 2\textsuperscript{nd} week of April 2017
KC Negotiations Module(s)

• The KC Negotiations module is maintained by Sponsored Projects Administration (SPA)
• Contains information on the various activities involved in setting up awards.
• 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, and the dates and responsible party associated with each action.
KC Negotiations Module(s)

- Currently “soft launched” with Federal and Non-Federal Contract and Grant Officers
- Collected feedback from administrator pilot group
- Soliciting Faculty feedback
- Will announce broadly, provide training and documentation after Faculty feedback
KC Negotiations Module(s)

Kuali Coeus Lookups
- Proposals Pending Preliminary Review
  - Displays all proposals in Preliminary Review queue
- Proposals Pending Institutional Review
  - Displays all proposals in Institutional Review queue
- Proposals to be Finalized
  - Displays all proposals to be Finalized
- KC Document Search
  - Search any Kuali document type using document ID
  - TIP: Filter with “Document Type”
- Development Proposal Lookup
  - Search development proposals
- Sponsor Code Lookup
  - Search for active sponsor codes. Please use the “New Sponsor Code Request” link to request codes.
- Status of Award Setup
  - Search Award Status Setup
- Status of Award Setup for PIs
  - Search Award Status Setup for Currently Logged in PI
### KC Negotiations Module(s)

<table>
<thead>
<tr>
<th>P2ID</th>
<th>Type</th>
<th>PI</th>
<th>Sponsor/Department/Agency/Institution</th>
<th>Activity</th>
<th>PI/Department Admin</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>206540</td>
<td>Grant</td>
<td>MICHAEL BERNS</td>
<td>OFFICE OF SCIENTIFIC RESEARCH (AFOSR)</td>
<td>Advanced Optical Technologies for</td>
<td>SHELLEY SCULLAN</td>
<td>Other</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Defense Trauma and Critical Care</td>
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<tr>
<td>207346</td>
<td>Contract</td>
<td>GABY THAI</td>
<td>UNIVERSITY OF SOUTHERN CALIFORNIA</td>
<td>Alzheimer's Disease Neuroimaging</td>
<td>PORPON LEKUTAI</td>
<td>PI/Department Admin</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Initiative 3 (ADNI3)</td>
<td></td>
<td></td>
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<tr>
<td>207060</td>
<td>Multiple Campus Subaward</td>
<td>SHELDON GREENFIELD</td>
<td>UC SAN FRANCISCO</td>
<td>Precision Medicine for Early Prostate Cancer: Integrating Biological a...</td>
<td>MARIA ANDRADE</td>
<td>HEALTH POLICY RESEARCH</td>
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<td>207855</td>
<td>Contract</td>
<td>DANIELE POMELLI</td>
<td>HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE</td>
<td>Evaluation of the Safety and Pharmacokinetics of the FAAH Inhibitor...</td>
<td>ROCQUEL GAINES</td>
<td>ANATOMY &amp; NEUROBIOLOGY</td>
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**Table:**

<table>
<thead>
<tr>
<th>Responsible Party</th>
<th>Action to be Taken</th>
<th>Activity Start Date</th>
<th>Activity End Date</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
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<td>Provide Additional Documentation/Information</td>
<td>01/31/2017</td>
<td>Requested PI to be included in Protocol</td>
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<td>SPA</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(s)

- Industry Clinical Trials
- Outgoing Subawards
KC Upgrade to KR

- On track to upgrade to KR June 2018
- User interface changes to Proposal Development only
- Going through code customizations
  - Looking for opportunities to streamline
- KC COI will continue operating with current interface
  - UCI is working with Kuali to further develop KR COI
Proposal: #722
PI: Not yet assigned

Proposal Details

Proposal Type: * New - Change/Corrected
Lead Unit: IN-CARD - CARDIOLOGY
Activity Type: * Research

Document was successfully saved.
<table>
<thead>
<tr>
<th><strong>Key Personnel</strong></th>
<th><strong>Lead Unit:</strong> IN-CARD - CARDIOLOGY</th>
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<tr>
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<td><strong>Credit Allocation</strong></td>
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<td><strong>Compliance</strong></td>
<td><strong>Project Title:</strong> This is the song that never ends</td>
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<td><strong>Attachments</strong></td>
<td><strong>Sponsor:</strong> 004090</td>
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<td><strong>Questionnaire</strong></td>
<td><strong>Prime Sponsor Code:</strong></td>
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<td><strong>Budget</strong></td>
<td><strong>Award ID:</strong></td>
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<td><strong>Access</strong></td>
<td><strong>Original Institutional Proposal ID:</strong></td>
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<td><strong>Supplemental Information</strong></td>
<td><strong>Keywords:</strong> Nothing selected</td>
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<td><strong>Summary/Submit</strong></td>
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<td><strong>Super User Actions</strong></td>
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### "Log Message" feature feedback

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<th>Annotation</th>
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<td>IN ACTION LIST</td>
<td>11:35 AM 03/29/2017</td>
<td>Action APPROVE generated by Workflow because wandak took action RETURNED TO PREVIOUS ROUTE LEVEL</td>
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</table>

<table>
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<tr>
<th>Log Action Message</th>
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</table>

<table>
<thead>
<tr>
<th>Action Message</th>
<th>log</th>
</tr>
</thead>
<tbody>
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<td></td>
<td></td>
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</tbody>
</table>
Poll – Do you like the Log Message Feature?
Grants.gov Workspace

- **Legacy PDF Application Package will be phased out in December 31, 2017.**
- Applicants will no longer be able to download the older, single PDF application package of forms.
- The new online forms interface will be added to Grants.gov and will only be accessible through Workspace in February 2017.
- For any funding opportunities where applicants have downloaded the legacy PDF application package, they will be able to continue to submit that package until March 31, 2018.
- S2S Submissions will continue to be supported.
- For more information about Grants.gov Workspace, please visit the various Workspace resources:
  - [Grants.gov Workspace Overview](#)
  - [Grants.gov Workspace Training Video Series](#)
  - [Grants.gov Community Blog articles on Workspace](#)
Grants.gov Workspace

• ERA will conduct communications and training in the Fall

• From previous slide: S2S submissions will continue to be supported…which means

• We encourage you to use Cayuse 424 for grants.gov applications
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The only way to make sense out of change is to plunge into it, move with it, and join the dance.
–Alan Watts

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

• NIH Operates Under a Continuing Resolution (NOT-OD-17-048) National Institutes of Health
  – The Department of Health and Human Services (HHS), including NIH, operates under the “Further Continuing and Security Assistance Appropriations Act, 2017,” (Public Law 114-254) signed by President Obama on December 10, 2016. This Act (CR) continues government operations through April 28, 2017 at 99.8099 percent of the FY 2016 enacted level.
  – … Per NOT-OD-17-049, the salary limitation set at Executive Level II of the Federal Pay Scale, was increased from $185,100 to $187,000, effective January 8, 2017.
  – The Ruth L. Kirschstein National Research Service Award postdoctoral stipend levels and tuition/fees for FY 2017 are described in NOT-OD-17-003. Until further notice, the undergraduate and predoctoral stipends and tuition/fees will remain at the levels announced in NOT-OD-16-062.
Interim Guidance on Salary Limitation for Grants and Cooperative Agreements (NOT-OD-17-049) National Institutes of Health

- ...The Consolidated Appropriations Act, 2016, restricts the amount of direct salary to Executive Level II of the Federal Executive pay scale. The Executive Level II salary was previously set at $185,100, and increased to $187,000 effective January 8, 2017.

- For awards issued in those years that were restricted to Executive Level II (see Salary Cap Summary, FY 1990 – FY 2016), including competing awards already issued in FY2017, if adequate funds are available in active awards, and if the salary cap increase is consistent with the institutional base salary, grantees may rebudget to accommodate the current Executive Level II salary level. However, no additional funds will be provided to these grant awards. ...
For applications submitted for due dates on or after January 25, 2017, text in PDF attachments must follow these minimum requirements:

- **Text Color**: No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.

- **Font size**: Must be 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%.

- **Type density**: Must be no more than 15 characters per linear inch (including characters and spaces).

- **Line spacing**: Must be no more than six lines per vertical inch.
NIH - Reminders

• Most Appendix Material for NIH/AHRQ/NIOSH Applications Eliminated (NOT-OD-16-129)

**Allowable appendix materials**
The only allowable appendix materials are:

– For applications proposing clinical trials (unless the FOA provides other instructions for these materials):
  • Clinical trial protocols
  • Investigator's brochure from Investigational New Drug (IND), as appropriate

– For all applications:
  • Blank informed consent/assent forms
  • Blank surveys, questionnaires, data collection instruments
  • FOA-specified items.
    – If appendix materials are required in the FOA, review criteria for that FOA will address those materials, and applications submitted without those appendix materials will be considered incomplete and will not be reviewed.

• Consequences for submitting disallowed appendix materials
Applications will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice or the FOA as allowed or required.
A new quarterly publication designed to provide information about upcoming changes and clarifications to policies and procedures that affect how you prepare and submit proposals and manage NSF awards has been released. The first issue of the NSF Proposal & Award Policy Newsletter is now available on the Policy Office website.
As of March 14, 2017, revised Research Terms and Conditions (RTCs) which address and implement the Uniform Guidance were announced by the U.S. Office of Management and Budget (OMB). In addition to the revised RTCs, some agencies have implemented Agency Specific Requirements (ASR) which supplements the RTCs.

The new RTCs and ASRs along with additional resources are being hosted by NSF and may be found at the NSF website at https://www.nsf.gov/awards/managing/rtc.jsp.

Please note that there are multiple implementation dates by Agencies participating in this effort. Specific Agency implementation dates and statements may be found at https://www.nsf.gov/bfa/dias/policy/fedrtc/agencyimpstatements_april17.pdf.

Additionally, other federal agencies may elect to implement ASRs in the future. Therefore, the NSF RTC website should be consulted frequently.
<table>
<thead>
<tr>
<th>AGENCY</th>
<th>IMPLEMENTATION DATE</th>
<th>APPLIES TO</th>
<th>EXCEPTIONS / NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>4/3/2017</td>
<td>All NIH grants and cooperative agreements.</td>
<td>Not all NIH awards will have the automatic carryover provision found in 2 CFR § 200.308(d)(3). Automatic carryover authority will be indicated on the Notice of Award (NoA).</td>
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<tr>
<td>NSF</td>
<td>4/3/2017</td>
<td>All new NSF grants and funding increments on existing NSF grants.</td>
<td>The RTC will not be applied to NSF cooperative agreements and fellowship awards made to individuals.</td>
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<tr>
<td>DOE</td>
<td>4/3/2017</td>
<td>All new grant and cooperative agreement awards subject to 2 CFR 210 as implemented by 2 CFR 910.</td>
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<tr>
<td>USDA - NIFA</td>
<td>6/1/2017</td>
<td>All awards (grants, cooperative agreements, and special projects) funded by NIFA except:</td>
<td>Existing research, education, and extension awards will continue to utilize the terms and conditions as stated in the award until the award expires unless the award receives a funding increment following June 1, 2017, in which case the core set of administrative terms and conditions and agency-specific terms dated June 2017 will apply to such awards.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1) Capacity Programs</td>
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<tr>
<td></td>
<td></td>
<td>2) the 1890 Facilities Program</td>
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<td>3) the Small Business Innovation Research Program</td>
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<td></td>
<td>4) awards to individuals.</td>
<td></td>
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<tr>
<td>NASA</td>
<td>10/1/2017</td>
<td>New awards</td>
<td></td>
</tr>
<tr>
<td>DOC</td>
<td>10/1/2017</td>
<td>All research financial assistance awards subject to 2 CFR Part 200.</td>
<td>Upon the issuance of a funded amendment or renewal, the Government-wide core set of research terms and conditions will be incorporated into the award.</td>
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<tr>
<td>FAA</td>
<td>10/1/2017</td>
<td>All new agreements</td>
<td>Agreements awarded prior to October 1, 2017 will use the terms and conditions stated in the current agreement.</td>
</tr>
<tr>
<td>EPA</td>
<td>Dec-17</td>
<td>Research grants and cooperative agreements awarded by the Office of Research and Development.</td>
<td>The standard Research terms and conditions will not apply to research centers, conferences, training projects, fellowships, or awards made as part of the People, Prosperity, and the Planet (P3) program.</td>
</tr>
</tbody>
</table>
QUESTIONS?
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Subrecipient Monitoring:
Best Practices

Grace J. Park, Subcontract Manager
Nina Crow, Subcontract Officer
Setting the Stage

• UCI, the Pass-through Entity (PTE), is responsible for ensuring that subrecipients comply with all applicable laws/regulations and the terms and conditions of the prime award

• UCI is required to monitoring the subrecipient as if it were the sponsor
What Exactly is Subaward Monitoring?

• Subrecipient v. Contractor Determination
• Monitoring of Subrecipient Activities
  – Review programmatic and financial reports
• Invoice Assessment/Payment
The Fine Print

Uniform Guidance sets forth the responsibilities and obligations of the Pass-through Entity:

- §200.305 Payment
- §200.330 Subrecipient and Contractor Determinations
- §200.331 Requirements for PTEs
- §200.332 Fixed Amount Subawards
- §200.338 Remedies for Noncompliance
Who’s on First?

• Some of the subrecipient monitoring responsibilities are handled by **Sponsored Projects** (such as risk analysis, visual compliance checks, financial audit reviews, etc.)

• **Principal Investigator** is responsible for monitoring technical progress of the subaward and the costs associated with it.

• Principal Investigator can delegate some of these responsibilities to **department administrators** (*except for certification of invoices – must be reviewed/signed by PI*)
Top Three Best Practices
3: Review Progress Reports

✓ Assess whether subrecipient is completing work in timely manner/milestones are being met
✓ Assess whether progress reports, when compared to invoices, reflect expenses that match up with progress of project
2. Review Invoices

✓ Assess whether the invoice is proper for payment
✓ Ensure timely payment of proper invoices
   • Approve and certify, in writing, all proper invoices received and forward to accounting to ensure timely payment
✓ Substantiate, reject and return improper invoices

Examples of improper invoices:
• Invoice is for 1/12 of annual budget, but progress reports don’t support level of expenses
• Invoice dates are not in line with the budget period
• Costs differ materially from the approved budget
2. Review Invoices (Contd.)

✓ Ensure final invoices are received timely and clearly marked “FINAL,” and forwarded to accounting to ensure timely closeout
  • Final invoice received for a fixed price subaward: ensure all project deliverables have been received and all milestones tied to payments have been achieved before final invoice is approved and certified
1. Communicate with Sponsored Projects

✓ Notify Sponsored Projects promptly regarding any non-compliance issues
  • Non-performance by subrecipient
  • Fraud or noncompliance with federal regulations
  • Subrecipient not fulfilling legal obligations of subaward agreement
Questions or Comments?
Thank you!

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Subaward Monitoring Guidelines
Agenda

• General Announcements
• Grants Management Group
• Research Engagement and Facilitation Update
• ERA Update
• Federal Update
• Subrecipient Monitoring: Best Practices
• Industry Clinical Trials Update
• Human Research Protections Update
• Contracts and Grants Accounting Update
Industry Clinical Trials Update

March 29, 2017
Industry Clinical Trials Team

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- All CDAs, non-master CTAs except for Depts. of Neurology, Dermatology, Pediatrics, IMIND

Heather Kubinec  
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949-824-9816  
- All amendments, all master CTAs, all CTAs for Depts. of Neurology, Dermatology, Pediatrics, IMIND

Clinical Trial Workflow Process
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
  – 700-U conflict of interest disclosure form
  – Draft budget
  – Protocol
  – Draft agreement

http://research.uci.edu/sponsored-projects/clinical-trials/starting-point.html
Submitting Required Documents to SPA

- Use the “Share Proposal” function to automatically generate an email with a link to the proposal. Add in the SPA industry clinical trial officer’s email address.
Example of KC Approval Route Log
Reminders

• COI: 700U form
  – If the CRO is a party to the agreement, ensure the Principal Investigator completes the form for both the Sponsor and CRO.

• Accelerated Clinical Trial Agreement (ACTA)
  – UCI has adopted the ACTA, which provides a standardized template for industry-sponsored, multi-center studies thus streamlining the contracting process. Please let sponsors know this and share the ACTA template with them when initiating discussions.
  – Access the template at www.ara4us.org or contact the SPA industry clinical trial team.

• Payment Terms
  – Please review the payment terms and ensure that they are consistent with the budget. We only review them for institutional issues.

• CDA processing
  – Let officer know if there are any unusual circumstances or concerns.

• If a sponsor notifies you that a study is on hold or is not moving forward, please let us know right away!
What’s new?

• **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 Kuali Coeus (budget and coverage analysis)

• **Status**
  – Testing and user feedback next month
  – Implementation by June 2017
## Negotiation Module Data Elements

### Negotiation Attributes
- **Negotiation Association Type**: Select
- **Negotiation Association IDs**:

### Regulatory Status
- IRB:
- COI:
- Approved IRB Document Received:

### Activities & Attachments
- **Add Activity**
  - **Activity Start Date**
  - **Follow-up Date**
  - **Status**: Select
  - **Activity End Date**
  - **Number of Days**
  - **Create Date**
  - **Last Update**

### Attachments
- **File**: Choose File, No file chosen
- **Description**:
  - Notification to SPA
  - Initial Letters Sent to Sponsor/CRO
  - SPA Received Response from Sponsor/CRO
  - Under Negotiation Between SPA and Sponsor/CRO
  - Contract Terms Finalized (Excluding Budget & Payment Terms)
  - Received Final Agreement
  - Contract to PI for Signature
  - Sent Partially Executed Agreement to Sponsor/CRO
  - Received Partially Executed Agreement from Sponsor/CRO
  - Sent Fully Executed Agreement to Sponsor
  - Received Fully Executed Agreement from Sponsor
  - Processed and Released to Accounting
  - Award Finalized in SPA Database & Synopsis Released

### Display
- **Sort By**: Select
- **Display**: All, Pending

### Activity/Location History
Principal Investigator/Department View
Questions?
Agenda

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- **Human Research Protections Update**
- Contracts and Grants Accounting Update
Topics of Discussion

• Good Clinical Practice Training requirement (NIH)
• CT.gov registration, updates, and penalties (HHS-FDA & NIH)
• Single IRB (sIRB) for NIH-funded Multi-Site Research (NIH)
• Revisions to the Common Rule (45 CFR 46 Subpart A)
NIH GCP Training Requirement

• Effective as of January 1, 2017 (applies to all active grants and contracts).

• All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP) – Int’l Conference on Harmonization (E6)

• UCI provides access to CITI FDA-focused GCP courses and the Best Practices in Social and Behavioral Research e-Learning Course for GCP through UCLC

• GCP Training is required every three years.
The Department of Health and Human Services (HHS) issued a new regulation, and the NIH issued a new policy, regarding registering clinical trials.

- **Registration**: Not later than 21 days after enrollment of the first participant.
- **Reporting Results**: Not later than 12 months after primary completion date
- Some **data elements must be updated more frequently** than annually such as Overall Recruitment Status, Individual Site Status, IRB Review Status and Completion Date.
HHS Regulations - CT.gov

- FDA-regulated drug, biological, and device products and pediatric post-market surveillance studies of devices required by the FDA under the FD&C Act.
- Does not apply to Phase 1 trials or small feasibility device studies.
- Applies to public and private sector sponsors, PIs, and institutions.
NIH Policy – CT.gov

• All clinical trials funded wholly or partially by NIH.
• Includes Phase 1 clinical trials and trials that do not involve any FDA regulated product such as trials involving only behavioral interventions.
• Effective January 18, 2017.
• Applies to NIH-funded clinical trials where applications or proposals are received by NIH on or after the effective date.
• Applies to NIH-conducted clinical trials initiated on or after the effective date.
CT.gov - Responsible Party

- Study Sponsor (if investigational drug/medical device)
- Principal investigator (if no sponsor – no IND/IDE)
- Grantee Institution if the research is NIH-funded
CT.gov Potential Consequences of Noncompliance

• HHS -
  – Identifying clinical trial record as non-compliant in ClinicalTrials.gov
  – For federally funded trials, grant funding can be withheld if required reporting cannot be verified
  – Civil monetary penalties of up to $10,000/day (amount to be adjusted going forward)

• NIH -
  – Identifying clinical trial record as non-compliant in ClinicalTrials.gov
  – May lead to suspension or termination of grant or contract funding
  – Noncompliance can be considered in future funding decisions
NIH Single IRB (sIRB) Requirement

- All sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH will use a sIRB
- Applies only to the domestic sites of NIH-funded multi-site studies
- Applicants are expected to include a plan for the use of an sIRB in the applications/proposals they submit to the NIH; or at JIT stage.
- Ongoing, non-competing awards will be expected to comply when submitting a competing renewal application.
- Effective September 25, 2017
Revised Common Rule
Subpart A 45 CFR 46

- Effective January 19, 2018
- Expands Exempt Research
- Eliminate Continuing Review of Minimal Risk Research
- sIRB for multi-site research (effective in January 20, 2020)
- Clinical trials consent form must be posted on a publicly available federal website
Revised Common Rule
Subpart A 45 CFR 46

Informed Consent Document must...

begin with a concise and focused presentation of key information that is most likely to assist prospective subject in understanding the reasons why one might or might not want to participate in the research.
Revised Common Rule
Subpart A 45 CFR 46

Informed Consent Document must include additional elements, as applicable...

• Indicate identifiers might be removed from identifiable private information or identifiable biospecimens and whether such information or biospecimens might or will not be used for future research studies.

• State whether biospecimens will be used for commercial profit

• Explain whether results will be disclosed to the subject

• Indicate whether the research might include whole genome sequencing
Resource

- UCI HRP NewsBrief – Winter 2017 @
Questions?
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• **Contracts and Grants Accounting Update**
Contracts and Grants Accounting Update

Beata Najman
Director, Extramural Funds Accounting
C&G Accounting Process Changes

• **Award Setup**
  If a detailed budget is included with Notice of Award, C&G Accounting will allocate funds to each budget category (e.g. salaries, benefits, travel) to help departments ensure budgetary controls and correct projections.

• **Payroll Certification**
  Payroll certification deadline is extended to 90 days from the actual budget period end date starting with the budget periods ending March 31, 2017.
C&G Accounting Process Changes

• Clinical Trials

Departments can request the following changes to the clinical trials billing:

- All clinical trials invoices, including an initial invoice, can be prepared by Department
- All checks can be sent to Department for deposits to be made by departmental staff

To initiate these changes to the process, departmental Manager should contact Gigi Bones mbones@uci.edu
C&G Accounting – New Tools

- Current unapplied checks and undistributed ACH payments can be researched by departments on C&G Accounting website under Undistributed Cash Deposits.

- Award Balance Overview (ABO) Principal Investigators can quickly see the financial standing of all of their active awards and projects.
Questions?
FAQ / Training

- What topic could you, or someone in your area, use training on?
- Is there a question that you, or someone in your area, frequently is asked or that is asked of Office of Research?
- 3-5 minute training video
NCURA Virtual Workshop - "Building a Budget"

• Group webinar Tuesday 04/04/2017
• 8:30AM-12:00PM
• Office of Research, 141 Innovation, Suite 250
• Register Today in UCLC (search NCURA)!

Learning Objectives:

• Using the Uniform Guidance as the basis for our discussion, this session will explore the foundations of budget building.
• Participants will discuss allowability, allocability, and reasonableness; administrative and clerical salary issues; determination of subrecipient, vendor, or consultant status; and many more issues surrounding budgeting, as well as crafting a solid budget justification.
• This workshop should lay the groundwork for Research Administrators to successfully and confidently collaborate with the PI to build a sound budget that reflects the scope of work.
See you next time...

Fall/Winter QRAM

- Date: Wednesday, August 30
- Time: 1:30-3:30
- Location: UCI Student Center - Emerald Bay A