Quality Research Administration Meeting

March 28, 2018
Agenda

- Introduction and Announcements
- KR Upgrade
- NIH Single IRB
- Update to NIH Human Subjects Requirements
- CT.gov
- Federal Update
- NSF PII Reporting Requirements for Inadvertent Disclosure
- C&G Accounting Update
- REF Update
- Introduction to Dimensions
- NIH Public Access Compliance
How did that make you feel?

Indifferent 50%
- Don’t really care
- On the fence
- Could be swayed either way

Happy 25%
- Glad
- Grateful
- Relieved

Unhappy 25%
- Irritated
- Uncomfortable
- Angry
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• NIH Public Access Compliance
Get ready
It’s coming
Where are you?

Indifferent 50%
- Don’t really care
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Unhappy 25%
- Irritated
- Uncomfortable
- Angry

Happy 25%
- Glad
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- Relieved
Upgrade to Kuali Research (KR)

April:
Internal Testing and Business Process Rewriting

May:
External Testing and Training Materials

June:
Hands on Training and Open Forum(s)

Go Live in KR:
Tuesday July 10, 2018
• Volunteer for testing in May
  – Let us know today!
  – Email era@research.uci.edu

• Sign up for a hands on training session in June
  – Register in UCLC; search KR Hands on Training
  – 9:00-12:00 in AIRB 1020
    • June 7, 12, 20 or 25

• Save the date: KR Upgrade Open Forums
  – Tuesday, June 19
  – Student Center, Emerald Bay B
  – Two sessions (AM/PM)
  – No registration
Questions?

Contact ERA at era@research.uci.edu
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NIH sIRB Policy

Karen Allen
Executive Director, Research Protections
NIH Single IRB (sIRB) Requirement

• Effective as of September 25, 2017

• 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; or at JIT stage

• Ongoing, non-competing awards will be expected to comply when submitting a competing renewal application
NIH Single IRB (sIRB) Requirement

Exceptions to the sIRB policy:

• Exempt research
• Excludes career development, research training or fellowship awards (“K”, “T”, and “F” grants)
• VA sites
• Foreign sites
• Sites involving tribal nations
• Sites for which review by the proposed sIRB is prohibited by a federal, tribal, or state law, regulation, or policy
• NIH will consider requests for exceptions if there is a compelling justification, but understand that exceptions will be rare
Lead Site/PI Responsibilities

Proposal Stage (At least 6-8 weeks before proposal deadline)

• Contact UCI’s sIRB Reliance Team at IRBReliance@uci.edu provide details about the study, including name of sites, the Master Protocol, and template consent document(s), grant deadline, role(s) UCI will play in the research (can attach a scope of work), whether this grant is for a single study, multiple studies and/or a network/consortium

• Determine whether UCI IRB can act as the single IRB (sIRB) or whether another external IRB would be appropriate. In general, UCI will only be the sIRB for multi-site research involving 4 or fewer sites.

• Determine whether Lead Site will be coordinating site. The coordinating site will work with the participating sites and the sIRB. The coordinating site and the Lead PI assume additional responsibilities when sIRB review is used.
Lead Site/PI Responsibilities

Proposal Stage (At least 6-8 weeks before proposal deadline)

- Include any sIRB fees and sIRB-related personnel costs in the grant budget, as well as appropriate budget justification information.
  - The IRB budget is based on the specifics of the research study including the number of sites, the anticipated duration of the study, and the anticipated number of modifications/amendments. UCI IRB has developed IRB fees for when we will serve as the sIRB.

- Obtain confirmation from the participating site investigators that his/her institution is willing to rely upon the specific identified IRB.
  - The participating site PI is responsible for contacting the appropriate office at his/her institution, obtaining confirmation of the institution’s willingness to rely on the sIRB, and communicating the confirmation to the lead PI. Lead PI may wish to provide other site PIs with a template Letter for Support to assist in obtaining and documenting IRB confirmation.
Lead Site/PI Responsibilities

Proposal Stage (At least 6-8 weeks before proposal deadline)

• Prepare a Single IRB Plan attachment for the grant/contract application. Plan includes:
  – Name of the sIRB of record.
  – Brief description of how communication between sites and the sIRB will be handled.
  – Statement that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
  – Description of which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.

• Fill out the grant application forms as required by NIH. See Section D “NIH Grant Application/Contract Proposal Preparation” of the NIH FAQ Single IRB Policy and Multi-site Research and (for specific details) Section 3.2 of the PHS Human Subjects and Clinical Trials Information Form Application Guide.
Participating/Relying Site/PI Responsibilities

Proposal Stage

1. Provide the lead (overall) PI with confirmation that the UCI is willing to rely upon the specific single IRB identified by the lead PI.

- Contact UCI sIRB Team **at least two weeks in advance** to request confirmation that the UCI is willing to rely on the sIRB selected by the lead site. To make the request, email the following information to IRBReliance@uci.edu.
  - The name of the UCI site investigator (site PI), the name of the lead PI, and the lead site
  - The proposed sIRB
  - The title of the study/grant and the grant deadline
  - A brief description of the study (can attach master protocol or draft portions of the grant proposal)
  - Whether this grant is for a single study, multiple studies and/or a network/consortium that will design and conduct studies
Participating/Relying Site/PI Responsibilities

Proposal Stage

• After assessing the acceptability of the proposed IRB, UCI IRB will provide the UCI participating investigator with an email or emailed Letter of Support. This should be retained for study records. If desired, a copy can be provided to the lead PI.

• Once the proposal is awarded, UCI participating investigator must submit an IRB Application along with all supporting documentation.

2. Fill out the grant application forms as required by NIH. See Section D “NIH Grant Application/Contract Proposal Preparation” of the NIH FAQ Single IRB Policy and Multi-site Research and (for specific details) Section 3.2 of the PHS Human Subjects and Clinical Trials Information Form Application Guide.
Questions?
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Update to NIH Human Subjects Requirements

School of Medicine Research Support Services

Presented by Mark Bourbonnais & Mike Murphy

March 28, 2018
NIH Changes That May Impact You

Pre-Award

• Identify if a study may be considered a clinical trial
• Select the correct opportunity announcement
• Complete the *NEW* Human Subjects Clinical Trials Information Form

Post-Award

• Register in clinicaltrials.gov
• Training in Good Clinical Practice
Purpose of Reforms & Policy Changes

**Efficiency**
Enhance the efficiency of how research studies involving human participants are conducted

**Transparency**
Promote a culture of transparency in research in order to advance public health

**Accountability**
Ensure that NIH can appropriately identify and report on their clinical trials portfolio to ensure proper stewardship

**Timely Reporting**
Decrease the time it takes investigators to publicly report study results
The NIH Definition of a Clinical Trial

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.

Learn more at: https://grants.nih.gov/policy/clinical-trials/definition.htm
The 4 KEY Questions We Must Ask

Does your study...

- Involve one or more **human subjects**?
- **Prospectively assign** human subject(s) to intervention(s)?
- Evaluate the **effect of intervention(s)** on the human subject(s)?
- Have a **health-related biomedical or behavioral outcome**?

If “yes” to ALL of these questions, your study is considered a clinical trial.
Let’s Take a Deeper Look into the Definition

• **Prospectively Assigned:** a pre-defined process specified in an approved protocol that stipulates the assignment of research subjects to one or more arms of a clinical trial.

• **Intervention:** a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes.

  *Examples include:*
  
  • Familiar = drugs, biologics, devices
  • Un-familiar = surgical techniques; behavioral therapies treatment/prevention/diagnostic strategies
Key Takeaways

• The NIH Definition of a Clinical Trial is **BROAD**
• Definition was expanded in October 2014
• *With broader definition, many more studies with human subjects may be classified as clinical trials*
• Encompasses a wide range of types of trials, including:
Need Help Determining if your Study is a Clinical Trial?

- Definition of Human Subjects Research
- Decision Tool
- Case Studies
- FAQs
- Decision Tree
- When in doubt, contact your Federal Officer
Change to Funding Opportunity Announcements (FOAs)

Effective January 25, 2018 – All grant applications & contract proposals involving one or more clinical trials must be submitted through an FOA or Request for Proposal (RFP) specifically designated for clinical trials

- all NIH opportunities either permit clinical trials (e.g., Parent R01 PA-18-345 or not (e.g., Parent R01 PA-18-484)
- Selecting the wrong announcement places the application at risk for administrative rejection.
Select the appropriate FOA for Clinical Trials

<table>
<thead>
<tr>
<th>FOA Title</th>
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</thead>
<tbody>
<tr>
<td>Participating Organization(s)</td>
</tr>
<tr>
<td>National Institutes of Health (NIH)</td>
</tr>
<tr>
<td>Components of Participating Organizations</td>
</tr>
<tr>
<td>National Cancer Institute (NCI)</td>
</tr>
<tr>
<td>Funding Opportunity Title</td>
</tr>
<tr>
<td>Early Phase Clinical Trials in Imaging and Image-Guided Interventions (R01 Clinical Trial Required)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FOA Section II. Award Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Types Allowed</td>
</tr>
<tr>
<td>New</td>
</tr>
<tr>
<td>Resubmission</td>
</tr>
<tr>
<td>Revision</td>
</tr>
<tr>
<td>The OER Glossary and the SF424 (R&amp;R) Application Guide provide details on application types.</td>
</tr>
<tr>
<td>Clinical Trial?</td>
</tr>
<tr>
<td>Required: Only accepting applications that propose clinical trial(s)</td>
</tr>
<tr>
<td>Need help determining whether you are doing a clinical trial?</td>
</tr>
</tbody>
</table>
The NEW Human Subjects Clinical Trials Information (HSCTI) Form

If ANY of the 4 criteria are met or if the study involves biospecimens, one or more sections of the information form are required.

The new HSCTI Form...

✓ Consolidates human subjects, inclusion enrollment, and clinical trial information into one form.
✓ Collects information at the study-level.
✓ Aligns with ClinicalTrials.gov (where possible) for future data exchange with ClinicalTrials.gov.
Completing the HSCTI form

- To avoid last-minute surprises, help faculty identify whether/which HSCTI sections apply to their proposal based on their responses to the 4 questions

<table>
<thead>
<tr>
<th>Form Section</th>
<th>If you answered &quot;yes&quot; to all the questions</th>
<th>If you answered &quot;no&quot; to any of the questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biospecimen statement</td>
<td>Not required</td>
<td>If all questions are “no” and study will use human specimens</td>
</tr>
<tr>
<td>Section 2 - Study Population Characteristics</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Section 3 - Protection and Monitoring Plans</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Section 4 - Protocol Synopsis</td>
<td>Required</td>
<td>Do not complete</td>
</tr>
<tr>
<td>Section 5 - Other Clinical Trial-related Attachments</td>
<td>Required if specified in the FOA</td>
<td>Do not complete</td>
</tr>
</tbody>
</table>
Next Steps...
Sign up for an interactive overview

School of Medicine Research Support Services will be hosting a detailed overview this April. For more information contact:

Michael Murphy,
Assistant Director, Research Support
School of Medicine
(949) 824-0216
mpmurphy@uci.edu
For questions, please contact:

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Director, Contracts & Grants
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(949) 682-5440
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Assistant Director, Research Support
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mpmurphy@uci.edu
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- NIH Public Access Compliance
The NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information covers all applications for funding (including grants, contracts, and other transactions) submitted on or after January 18, 2017 that request support for the conduct of any clinical trial. The policy does not apply to clinical trials in ongoing, non-competing awards, but will apply if the grantee submits a competing renewal application that includes a new clinical trial. The policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.

Although the policy does not apply to NIH-funded clinical trials initiated before the effective date, NIH encourages all ongoing NIH-funded clinical trials to follow this policy. Investigators conducting NIH-funded applicable clinical trials that are subject to the statute* and rule** also need to be in compliance with those requirements.

The policy applies:
- to all applications for funding (including grants, contracts, and other transactions) submitted on or after January 18, 2017 that request support for the conduct of any clinical trial
- if the grantee submits a competing renewal application that includes a new clinical trial

The policy does not apply to:
- clinical trials in ongoing, non-competing awards
- a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct
- NIH-funded clinical trials initiated before the effective date

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2 https://grants.nih.gov/policy/clinical-trials/reporting/faq.htm#5053
5 HHS Agencies (includes NIH): https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html
* FDAAA, ** Final Rule / 42 CFR Part 11
* Specific to a funding opportunity announcement (FOA)
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.

1 https://www.federalregister.gov/d/2016-22379/p-70
2 https://grants.nih.gov/policy/clinical-trials/definition.htm

Unpacking the definition (slides 5 & 6): https://grants.nih.gov/sites/default/files/Clinical-Trials-Changes-full%20length_v5.pptx


FAQs: https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm

March 2018 - possible update to definition for basic behavioral research:
NIH POLICY

Responsible Party 1, 2, 3

NIH-Funded Clinical Trial is subject only to the NIH Policy:
- The recipient or investigator

NIH-Funded Clinical Trial is subject to the DHHS Final Rule:
- The Sponsor, or
- The Principal Investigator, if designated by the sponsor, grantee, contractor, or awardee

Registration at ClinicalTrials.gov: within 21 days after enrollment of the first research participant 4

Results Submission at ClinicalTrials.gov: within 12 months after primary completion date 5

2 https://grants.nih.gov/policy/clinical-trials/reporting/steps.htm#
3 https://www.federalregister.gov/d/2016-22379/p-74
4 https://clinicaltrials.gov/ct2/manage-recs/faq#fr_5
5 https://clinicaltrials.gov/ct2/manage-recs/faq#fr_7


Noncompliance (page 6), 2016 NEJM article: The FDAAA and the NIH policy hold all parties responsible for clinical trials (not just the individual investigators) accountable. [DOI: 10.1056/NEJMr1611785]
**Applicable Device Clinical Trial**
1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric postmarket surveillance required by FDA

**Applicable Drug Clinical Trial**
Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation

**A note about Expanded Access**
Information on the availability of investigational drug products (including biological drug products) for expanded access will continue to be required to be submitted to the Clinical Trials.gov database.

FAQs: [https://clinicaltrials.gov/ct2/manage-recs/faq](https://clinicaltrials.gov/ct2/manage-recs/faq)

2. [https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered](https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered)
3. [https://grants.nih.gov/clinicaltrials_fdaaa/docs/Flow_chart-ACT_only.pdf](https://grants.nih.gov/clinicaltrials_fdaaa/docs/Flow_chart-ACT_only.pdf)
DHHS FINAL RULE

Responsible Party \(^1, \, 2\)

- The Sponsor, or
- The Principal Investigator, if designated by the sponsor, grantee, contractor, or awardee

**Final Rule: effective January 18, 2017 / compliance date of April 18, 2017**

**Registration at ClinicalTrials.gov:** within 21 days after enrollment of the first research participant \(^3, \, 4\)

**Results Submission at ClinicalTrials.gov:** within 12 months after primary completion date \(^5, \, 6\)


\(^2\) [https://clinicaltrials.gov/ct2/manage-recs/fdaa#WhoIsResponsibleForRegistering](https://clinicaltrials.gov/ct2/manage-recs/fdaa#WhoIsResponsibleForRegistering)


\(^4\) [https://clinicaltrials.gov/ct2/manage-recs/faq#fr_5](https://clinicaltrials.gov/ct2/manage-recs/faq#fr_5)


\(^6\) [https://clinicaltrials.gov/ct2/manage-recs/faq#fr_7](https://clinicaltrials.gov/ct2/manage-recs/faq#fr_7)

**FAQs:** [https://clinicaltrials.gov/ct2/manage-recs/faq](https://clinicaltrials.gov/ct2/manage-recs/faq)

**Registration & Results submission - table (prior to 2007, and on/after effective date of final rule):** [https://www.federalregister.gov/d/2016-22129/p-961](https://www.federalregister.gov/d/2016-22129/p-961)


Noncompliance (page 6), *2016 NEJM article:* The FDAAA and the NIH policy hold all parties responsible for clinical trials (not just the individual investigators) accountable. [DOI: 10.1056/NEJMsr1611785]
Human Research meets conditions of the **NIH Policy**

- Register at [ClinicalTrials.gov](https://ClinicalTrials.gov) within 21 days of enrollment of first research subject
- Submit **Study Results** at [ClinicalTrials.gov](https://ClinicalTrials.gov) within 12 months after completion of research study

Human Research meets conditions of the **DHHS Final Rule**

- Register at [ClinicalTrials.gov](https://ClinicalTrials.gov) within 21 days of enrollment of first research subject
- Submit **Study Results** at [ClinicalTrials.gov](https://ClinicalTrials.gov) within 12 months after completion of research study
School of Medicine clinical trials: Mark Bourbonnais (Mbournon@hs.uci.edu, 949-682-5440)

Non-School of Medicine clinical trials: Laverne Estanol (Lestanol@uci.edu, 949-824-4704)

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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
• NSF Research.gov Proposal Preparation Site Preview Now Available
  – NSF is previewing the new Research.gov proposal preparation functionality to the research community to collect preliminary feedback and to provide the community an opportunity to acclimate to the new technology.
• Revision of NSF Terms and Conditions
  – Modification of Research.gov to include an “Other” category, which must be used to submit prior approval requirements that do not already have a specific request type in NSF’s electronic systems. Revision of eligibility standards for foreign organizations; and
  – New requirement for grantees to have procedures in place to respond to a breach of personally identifiable information (PII) and notify NSF that a breach of PII within the scope of an NSF award has occurred (to be discussed in more detail later in QRAM session
  – The revised Terms and Conditions applies to all new NSF awards and funding amendments to existing NSF awards made on or after March 1, 2018.
NIH Reminder

• Timely Grant Closeout is important
QUESTIONS?
Proposed NSF Award Term

Reporting Requirements Regarding Findings of Sexual Harassment, Other Forms of Harassment, or Sexual Assault
Purpose and Application of Proposed Award Term

- Intended to ensure grantee compliance with federal non-discrimination laws

- Applies to all recipients of NSF funds

- Applies to all locations and sites where NSF sponsored activities are carried out - including on-line
Key Elements of Proposed Award Term

● Grantees must notify NSF if
  ○ Any PI or Co-PI is found - or determined - to have violated, grantee codes of conduct or policies, regulations or statutes relating to any form of harassment or sexual assault, or
  ○ The grantee places any PI or Co-PI on administrative leave relating to an investigation or finding of a violation of the same.

● Notification must be made within seven business days from the date of the finding or determination, or placement on administrative leave

● Requires that grantees make appropriate arrangements to ensure the safety of other award personnel, as well as continued progress of the funded project.
Potential Consequences for Non-compliance

● NSF may take unilateral action:
  ○ Requiring substitution of the PI or Co-PI
  ○ Requiring removal of Co-PI
  ○ Reduction of award funds
  ○ Suspension of the award
  ○ Award termination
Comments

- Comments are due on May 4, 2018
- UC will be providing coordinated comments
- Council on Governmental Relations will be commenting in conjunction with other academic organizations (AAU, AAAS, etc.)

Our office will keep you informed of future developments regarding this proposed award term.
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NSF PII Reporting Requirements for Inadvertent Disclosure

Isaac Straley
Chief Information Security Officer
Incident Response Procedures

• If it is still in your possession, remove the computing system from the campus network.
• Do not turn the system off / shut it down.
• Do not run anti-virus, anti-spyware, or other "cleaning" tools.
• **Campus:** Contact the OIT Help Desk at (949) 824-2222 to report that a potential data breach has occurred and request immediate notification of the **OIT Security Team** and the **Security Breach Lead Campus Authorities**. Send detailed information to security@uci.edu and security-lca@uci.edu.
• **UCI Health:** If you think there has been a HIPAA violation, please use the confidential line to report it to UC Irvine's Health Privacy Officer at 1-888-456-7006 or contact the UCI Health Service Desk at 714-456-3333 and request the Data Security team.
Incident Response Procedures

Stolen Computer, Laptop, Phone, Tablet, or other Device
• File a report with the UC Irvine Police Department.
• If you a university employee, report it to your supervisor or school administration.
• If you have university restricted data, immediately follow the data breach process above.

UCInetID Compromised
• If you think your UCInetID password has been stolen or your account has been inappropriately accessed:
  • Immediately reset your password.
  • Notify the OIT Security Team by emailing security@uci.edu or contact the UCI Health Service Desk at 714-456-3333 and request the Data Security team.
• If you are University staff, also notify your supervisor.
• If appropriate, file a report with the UC Irvine Police Department.
Incident Response – Local Plan

Responsibilities - Identify key individuals and ensure they have the authority to make hard decisions and act timely in an incident.
  - Who coordinates incident response
  - Who informs security and who informs sponsors
  - Who manages internal workflow

Inventory - You can't protect what you don't know exists. If a computer is compromised, you should be able to easily know and identify if it has restricted data.
  - What and where are critical assets
  - Who works with sensitive and restricted data

Implementation - Ensure the actual incident response steps are clearly documented, understood, and tested.
  - A documented workflow for handling incidents

Recovery - A critical step in incident response is getting a system back online. Example: What happens if a system is compromised and must be removed for a forensics investigation?
  - How do you get back online after an incident (both small and large)
  - Tie to Disaster Recovery / Business Continuity Plans

Training - Ensure all individuals understand how to detect and report an incident.
  - How to determine an infection / incident and when to report
  - Who receives the reports
Incident Response References

- https://security.uci.edu/incident.html
- http://www.policies.uci.edu/policies/procs/800-17.html
- https://security.uci.edu/security-plan/plan-incident.html
- https://www.ucop.edu/information-technology-services/_files/uc_incidentresp_plan.pdf
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Contracts and Grants Accounting Update

Beata Najman
External Audits

An External Audit is a periodic or specific purpose audit conducted by external (independent) qualified accountant(s). Its objective is to determine, among other things, whether:

• the accounting records are accurate and complete,
• prepared in accordance with generally accepted accounting principles, and
• the statements prepared from the accounts present fairly the organization's financial position, and the results of its financial operations.
External Audits – Departmental Responsibilities

- Do not provide any information over the telephone
- Notify Contracts and Grants Accounting
- Recommend key departmental personnel for explaining departmental and campus processes
- Review and prepare related records
- Provide well-ordered, clear documents
- Be prepared for the meeting and understand the purpose of the meeting
- Respond only to the question being asked, and keep your answers simple and direct
- If, in the course of an audit, errors are discovered, process corrections immediately.
External Audits – C&G Accounting

• Contact the external auditor to determine purpose, timing, and scope of audit
• Coordinate opening meeting with appropriate personnel (departmental financial personnel, programmatic personnel, central administrative personnel, etc.)
• Respond to requests for information by working with campus departments and central administrative units
• Review materials for completeness, compliance, and reasonableness
• Respond to any questions regarding the materials provided and provide additional materials as necessary
• Prepare the campus response to any findings reported by the external auditors
• Request corrective actions from departments when inappropriate charges and/or processes are discovered.
NIH Unilateral Closeout

• Enforcement of Closeout Policies (NOT-OD-18-107)
  – Issued November 30, 2017
  – Grantees are required to submit timely and accurate final grant expenditure reports, and to reconcile cash transaction reports submitted to the HHS Payment Management System (PMS) with expenditure reports submitted to NIH.
  – NIH will no longer delay the closeout of awards unless the recipient submits a prior approval request to the NIH Institute and Center (IC) providing an acceptable written justification. Without prior approval from the awarding IC, NIH will initiate unilateral closeout for all awards that fail to meet closeout requirements within 120 days.
NIH Unilateral Closeout – Financial Impact

- Timely Award Financial Reporting and Closeout
  • Expenses must be posted to the ledger in order for them to be captured in the final Federal Financial Report (FFR) submitted to NIH
  • NIH will no longer permit Grantees to reopen reports and report additional expenditures
  • NIH will close the grant using the last accepted Federal Cash Transaction Report’s cash drawdown amount.

- HRSA awards, and awards with funds reverting back to the US Treasury at the end of the grant final budget period require that all closeout actions take place prior to the expiration date of the award. The 120-days closeout period does not apply to these awards.
Stipends vs. Salaries

• NIH Grants Policy Statement

Stipends are not allowable under research grants even if they appear to benefit the research project.

• Distinguishing Between Stipends, Salaries and Wages for Student Compensation

## Stipends
- Financial assistance or support paid to university students; no work assigned.
- No scope of work.
- No required fringe benefits or remissions.
- Student-mentor relationship; no employer-employee relationship.
- No grant and contract support unless the purpose of the award is to provide fellowship or scholarship.

## Salaries and Wages
- Compensation for performance of assigned work.
- Scope of work assigned.
- Applicable UC employee fringe benefits and Fee Remission as appropriate based on eligibility.
- Employer-employee relationship, and salary amounts restricted by University salary scales.
- Can be paid from grant and contract funds, and other internal funding sources.
Questions?
Agenda

- Introduction and Announcements
- KR Upgrade
- NIH Single IRB
- Update to NIH Human Subjects Requirements
- CT.gov
- Federal Update
- NSF PII Reporting Requirements for Inadvertent Disclosure
- C&G Accounting Update
- **REF Update**
- Introduction to Dimensions
- NIH Public Access Compliance
REF Update

Nadia Wong
COI Administrator
Joint 700U/IRB Projects- Tips

In March, we sent some tips and additional clarification to the IRB and SPA listservs on this new process based on feedback from IRB, SPA, and campus department administrators.

Please pick up a handout and share with your office.
Highlights

• Start and save the KC proposal first so you can include the KC proposal number in the IRB protocol application.

• Answer the questions in the IRB protocol application and corresponding KC proposal carefully. If you have any questions, please contact the COI team directly.

• Do not label the Form 700U attachment as “Other” because the electronic system cannot identify it appropriately.
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Dimensions for Universities

- You can start using this new platform now by visiting: https://app.dimensions.ai/

- Dimensions is a linked research data platform, including information on publications, research funding, patents and clinical trials - all on an international scale.

- Use Cases:
  - Discovery of the latest publications, awarded grant funding, clinical trials or patents on any topic of interest, worldwide.
  - Benchmarking of research organizations, funders, publications or researchers in a particular topic, or across all research activity.
  - Identification of new sources of research funding for future funding applications
  - Clear and unbiased analysis of the research activity at our own organization, and how this is changing over time.

- Available through UCI IP ranges, but working on implementing Single Sign On (SSO).

- View the “Quick Start Guide” video which describes how Dimensions can be used. The video can be viewed by clicking here.
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Any final questions or comments?
See you next time...

Summer/Fall QRAM

• Date: Wednesday, August 29, 2018
• Time: 1:30-3:30
• Location: UCI Student Center – Doheny Beach B