Agenda

• General Announcements
• Chart of Accounts Maintenance Demonstration
• Human Research Protections Update
• Research Engagement and Facilitation (REF) Update
• Federal Update
• Foundation Relations
• ERA Update
• Office of Research closed:
  – December 25, 2017-January 2, 2018
• Contacts:
  – Sponsored Projects: era@research.uci.edu
  – Research Protections:
    • IACUC@research.uci.edu
    • hSCRO@research.uci.edu
    • IRB@research.uci.edu
Agenda

• General Announcements

• **Chart of Accounts Maintenance Demonstration**

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Human Research Protections Update

December 2017

Karen Allen
Executive Director, Research Protections
What’s New...

• Undergraduate Research
• Revisions to the Common Rule (OHRP)
• Certificates of Confidentiality (NIH)
• Single IRB (sIRB) for NIH-funded Multi-Site Research
• CT.gov registration, updates, and penalties (HHS-FDA & NIH)
• Single IRB (sIRB) for Industry-Sponsored Research
Undergraduate Research

• UROP will assume responsibility for confirmation of most exempt level research where undergraduate is the Lead Researcher with Faculty Sponsorship

• Effective with UROP 2017 Fall Call for Proposals
Revised Common Rule
Subpart A 45 CFR 46

- The intent of the revisions is to “modernize, strengthen, and make more effective” the current system of oversight that has been the federal “Common Rule” since 1991. The revisions are intended to:
  - Better protect human subjects involved in research
  - Facilitate research
  - Remove ambiguity
  - Reduce regulatory burden
Revised Common Rule
Subpart A 45 CFR 46

• Effective January 19, 2018

• Expands Exempt Research, includes limited IRB Review provision

• Eliminates Continuing Review for Minimal Risk Research

• Requires concise and focused summary of key information during informed consent

• Additional elements of informed consent – use of biospecimens, commercial use, whole genome sequencing
Exempt Research

• Lots of changes…
  – Changes to Categories 1, 2 & 4
  – New Categories 3, 7 & 8
  – Researcher able to self-determine

Exempt status there are some exceptions
Expedited Research - Eliminate Continuing Review

• Continuing review is **not** required for minimal risk research (research approved under Exempt Limited IRB review or Expedited)
  – *Unless the IRB explicitly provides written justification*

• UCI HRP will administratively review ongoing Exempt and Expedited research every three years. We will require a “short” continuing application; 5-6 questions multiple choice questions.

• Researchers still have the obligation to report modifications, unanticipated problems, noncompliance, complaints, etc.

• **NOTE:** FDA has not adopted Common Rule changes…yet. At least annual review of FDA-regulated, minimal risk research is still required.
Proposed Delay to Common Rule Implementation

• On October 7, 2017, HHS proposed a one-year delay of the general implementation date (while allowing the use of three burden-reducing provisions during the delay year).
  – This would delay the implementation date to January 19, 2019.
  – The three “burden-reducing provisions” were not specified in the request.

• The proposed delay is currently under review by the Office of Management and Budget (OMB).
NIH Certificate of Confidentiality

- Effective October 1, 2017

- Research funded wholly or in part by NIH involving the collection or use identifiable, sensitive information will automatically receive a CoC (including grants, cooperative agreements, and contracts)

- NIH-funded research that started or was ongoing on or after December 13, 2016 and is within the scope of the policy automatically issued a CoC. No "certificate" will be issued.

- Consent form must include CoC language.

- Responsibilities of CoCs transfer to subrecipients and others who receive identifiable data and biospecimens, even if their activities are not funded by NIH.

- Non-HHS supported research may still apply for a CoC through the NIH Institute/Center that supports research in a similar scientific area.
NIH Single IRB (sIRB) Requirement

• Effective January 25, 2018

• NIH applicants of multi-site clinical studies where each site will conduct the same protocol

• Applies to the domestic sites funded through grants, cooperative agreements, or contracts (includes new, renewal, revisions, or resubmissions)

• Applicants are expected to include a plan for the use of an sIRB in the applications/proposals

• Contact Valerie Sanchez, IRB Reliance Administrator 949-824-7735 / IRBReliance@uci.edu to discuss UCI IRB being the sIRB or whether an external IRB would be appropriate.
ClinicalTrials.gov Registration and Reporting

Key Clinical Trial Reporting Requirements

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<td>Results: Not later than 1 year after Primary Completion Date (some Delays permitted)</td>
<td>Results: Not later than 1 year after Primary Completion Date (some Delays permitted)</td>
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<td>Enforcement</td>
<td>Refusal to publish</td>
<td>Criminal proceedings and civil penalties (up to $10,000/day); Loss of HHS funding to grantee institution</td>
<td>Loss of NIH funding (term and condition of award)</td>
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Industry-Authored Clinical Trials

• Allow use of independent sIRB for multi-site, industry-authored, clinical trials (currently allow Phase 2b and above; allow all phases for oncology clinical trials).

• Use Sponsors preferred IRB

• UCI has signed Master IRB agreements with:
  – Western IRB (includes Copernicus, Aspire, Midlands, and New England IRBs)
  – Quorum IRB
  – Shulman IRB and Chesapeake IRB (recently merged to form Advarra IRB)
Questions?
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Export Control Updates

Marci Copeland
Research Engagement & Facilitation
(REF)
Transactions Involving Sanctioned Countries

United States sanctions programs are administered by the U.S. Department of Treasury, Office of Foreign Assets Control (OFAC), and impact our university activities.

The most restrictive sanctions programs (Cuba, Iran, North Korea, Sudan and Syria) prohibit U.S. Persons from:

- A broad range of services and transactions that benefit or provide value.
- Export of products, software, and transfer of technology.
- Providing educational services and technical services, even where no monetary compensation occurs.
Sanctions Regulations Apply to U.S. Persons

U.S. Persons:

- Any person within the U.S.
- Any U.S. citizen or permanent resident alien, wherever physically located
- Any entity or institution organized under U.S. law, including foreign branches

There are General Licenses for some activities and Specific Licenses can be obtained from OFAC in many cases.
What does this mean?

Record keeping for five years is required by the regulations.
Action needed

Faculty, staff and students, contact the Export Control Officer for guidance as soon as possible, for any of the following, involving a comprehensively sanctioned country:

• any imports/exports (examples include research samples, artwork, or equipment)
• collaboration with entities in a sanctioned country
• research in
• travel to (including to attend a conference)
• transfer of funds to
Transactions involving restricted entities

The U.S. government maintains a number of lists of federally sanctioned, debarred or restricted persons and organizations such as:

- The Specially Designated Nationals and Blocked Persons List (U.S. Department of Treasury);
- The Foreign Sanctions Evaders List (U.S. Department of Treasury);
- The Entity List (U.S. Department of Commerce);
- The Denied Persons List (U.S. Department of Commerce);
- The Unverified List (U.S. Department of Commerce);
- The Nonproliferation Sanctions List (U.S. Department of State);
- The AECA Debarred List (U.S. Department of State).
Sponsored Research/IT Security Update

Marci Copeland
Research Engagement & Facilitation
(REF)
Controlled Unclassified Information (CUI) Program

- Defined by Executive Order 13556, published November 4, 2010
- Prior to EO 13556 more than 100 different markings for such information existed across the executive branch

Established the National Archives and Records Administration (NARA) as the Executive Agent for CUI
  - Create CUI Registry
  - Develop directives to implement CUI program (NIST 800-171)
The CUI Registry

Features:
CUI categories
CUI subcategories
CUI change log
  – 4 updates to the CUI registry so far in 2017

CUI Limited Dissemination Controls
Examples of markings
  – No foreign dissemination (NORFORN)
  – Federal Employees Only (FED ONLY)
CUI Examples

Controlled Technical Information

Information with military or space application that is subject to controls on the access, use, reproduction, modification, performance, display, release, disclosure, or dissemination. **Controlled technical information is to be marked with one of the distribution statements B through F, in accordance with Department of Defense Instruction 5230.24, "Distribution Statements of Technical Documents."

The term does not include information that is lawfully publicly available without restrictions. "Technical Information" means technical data or computer software, as those terms are defined in Defense Federal Acquisition Regulation Supplement clause 252.227-7013, "Rights in Technical Data - Noncommercial Items" (48 CFR 252.227-7013).

Examples of technical information include research and engineering data, engineering drawings, and associated lists, specifications, standards, process sheets, manuals, technical reports, technical orders, catalog-item identifications, data sets, studies and analyses and related information, and computer software executable code and source code.
CUI Examples

Law Enforcement – Criminal History Records
Related to information collected by criminal justice agencies on individuals consisting of identifiable descriptions and notations of arrests, detentions, indictments, informations, or other formal criminal charges, and any disposition arising therefrom, including acquittal, sentencing, correctional supervision, and release.

Geodetic Product Information
Related to imagery, imagery intelligence, or geospatial information.
CUI Examples

Immigration-Asylee
Related to admission of non-US citizens into the United States and applications for temporary and permanent residency.

Census Data
Related to information gathered by the Bureau of the Census during the process of collecting, compiling, evaluating, analyzing of demographic, economic, and social data pertaining, at a specified time, to any or all persons in the United States.
When are CUI/800-171 requirements applicable?

Currently through
• Defense Federal Acquisition Regulation (DFAR) 7012 (most recent Oct 2016) Safeguarding Covered Defense Information and Cyber Incident Reporting, requires full compliance by December 31, 2017
• May be referenced in an agreement in an ad hoc way: research agreements, data use agreements, non-disclosure agreements. Anticipate research utilizing information from the categories described will include references to 800-171 in future agreements such as data use agreements.

Coming soon
• NARA will sponsor a single Federal Acquisition Regulation (FAR) clause that will apply the requirements in proposed CUI regulation and Special Publication 800-171 to contractors
Research Engagement & Facilitation Team

- 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, such as faculty meetings, to create awareness and engagement
• Ideas on how to better communicate with campus
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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
Staff Changes

• New Contract and Grant Analyst
  – Sennite Meche
• NSF Proposal & Award Policies & Procedures Guide (PAPPG) (Effective January 2018)
  – The new PAPPG will be effective for proposals submitted, or due, on or after January 29, 2018. Significant changes include:
    • Addition of a new eligibility subcategory on international branch campuses of U.S. Institutions of Higher Education;
    • Revision of eligibility standards for foreign organizations;
    • Implementation of the standard Collaborators and Other Affiliations (COA) template that has been in pilot phase since April;
    • Increase in the Budget Justification page limitation from three pages to five pages;
    • Restructuring of coverage on grantee notifications to and requests for approval from NSF, including referral to the Prior Approval Matrix available on the NSF website; and
    • Numerous clarifications and other changes throughout the document.
  – A webinar to brief the community on the new PAPPG will be held on December 8 at 2 PM EST. Our ERA team will be broadcasting from the Office of Research.
NIH Reminder

• 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

• New Application Packages (FORMS-E)
  – Applies to NIH and AHRQ
  – 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
  – All NIH "parent" announcements that use standard due dates will be expired and reissued with new FOA numbers, FORMS-E application packages and instructions.
• Revised Grants Policy Statement for FY 2018
  – Applicable to all NIH Grants and Cooperative Agreements with budget periods beginning October 1, 2017
  – Update incorporates new and modified requirements and clarifies certain policies.
NIH

- **Enforcement of Closeout Policies (NOT-OD-18-107)**
  - Issued November 30, 2017
  - In order to fulfill agency requirements under the Grants Oversight and New Efficiency (GONE) Act and HHS grants policy, NIH will no longer delay the closeout of awards unless the recipient submits a prior approval request to the 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.
What will happen if a PI fails to submit a Final Research Performance Progress Report (Final RPPR) and/or a Final Invention Statement and Certification (FIS)?

- When attempts to collect F-RPPR or FIS are exhausted, NIH may take unilateral action to close the grant and/or impose sanctions for recurring reporting problems. Such sanctions may include, but are not limited to, corrective actions, removal of authorities, and/or delay or withholding of future awards.
NIH

Financial Impact:

– Timely award financial reporting and closeout
  • Expenses must be posted to the ledger within 90 days in order for them to be captured in the final financial report (FFR) submitted to NIH.
  • To allow cash drawdown and financial closeout of the award, C&G Accounting is required to match all financial records to the ledger before the 120 days reporting deadline.
  • NIH will no longer permit Grantees to reopen reports and report additional expenditures.
QUESTIONS?
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Foundation Relations

Roxanne Ford
Exec. Director, Foundation & Corporate Relations
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- Foundation Relations
- **ERA Update**
ERA Updates

Bruce Morgan
Jonathan Lew
Nancy Lewis
Who are we?

Barbara Inderwiesche
Alison Yeung
Kim Frazer
Jonathan Lew
Martin Nakatsu
...and what do we do?
Research Administration System Support

• ERA helps faculty and staff activate user accounts for internal and external systems, and provides ongoing system support and training.

• Systems include, but are not limited to:
  – Internal Systems
    • Kuali Coeus (KC): Proposal Development, Negotiations, Conflict of Interest
    • Research Management System (RMS): IACUC protocols and animal management
    • Cayuse 424
    • Research Administration Data Warehouse
    • Cognos
  – External Systems
    • Grants.gov
    • NIH eRA Commons
    • NSF Fastlane
    • ProposalCENTRAL
    • FedConnect
    • NASA NSPIRES
    • Other Agency Systems
Decision Support and Institutional Reporting

• ERA produces institutional reports for awards and proposals. ERA collaborates with data stakeholders to design and implement decision support and grants management tools to facilitate administration of research.
Data Integrity and Stewardship

• ERA ensures data integrity by overseeing the maintenance, accuracy and consistency of proposal, award, protocol and financial disclosure data during the research project life-cycle. ERA works hard to ensure consistency access to high-quality research administration data.
Training and Communication

• Maintains UCI Office of Research YouTube page. Subscribe today!

• Plans and facilitates Quarterly Research Administration Meetings (QRAM)

• Hosts monthly ERA Office Hours. Sign up by searching “ERA” in uclc.uci.edu

• Communicates system status to campus users
Enterprise System Implementation

• ERA leads the way in implementing new functionality in UCI’s enterprise systems as part of the Office of Research’s ongoing efforts to streamline processes and reduce regulatory and administrative burden on faculty and staff.
Contact us at:

era@research.uci.edu
PI/Co-PI Credit Report
PI / Co-PI Credit Report

• Credit = 100% of the total award amount allocated to each PI and Co-PI(s).
  – Example: we receive a $1M award for PI, Co-PI(1) and Co-PI(2). In the credit report, PI credit is $1M, Co-PI(1) credit is $1M and Co-PI(2) credit is $1M.

• Includes all PIs and Co-PIs as entered in Kuali Coeus Proposal Development documents.

• The dollar amounts reflects the Total Costs of the award transactions that are processed in a particular Fiscal Year (ie. Based on process date, not performance start / end dates)
Updates to Campus Data Warehouse
New fields added to Sponsored Projects Adhoc Query

New Award fields added:
- Award PI Campus ID
- Award Prime Sponsor Code
- Award Prime Sponsor Name
- Award Prime Sponsor Category Code
- Award Prime Category Description
- Award Clinical Trial Phase

• New Proposal fields added:
  - Proposal PI Campus ID
  - Proposal Prime Sponsor Code
  - Proposal Prime Sponsor Name
  - Proposal Prime Sponsor Category Code
  - Proposal Prime Category Description
Cayuse 424 v.8.0

- Deployed this Saturday, Dec. 9th
  - New FORMS-E
  - Updated opportunity-specific validations
  - Any proposals you’ve started already, you can transform

**Click ‘Download Opportunities’ each time you create a new proposal to ensure you get the most up-to-date application package**
RMS Updates

Martin Nakatsu
IACUC Protocol UI Changes

• Streamlined and optimized the management of the IACUC protocol forms
• Reduced the clicks to access protocols and perform actions
  – No more right-clicking!
• Go live date: Dec 18th, 2017
# of entries: 1

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Documents/ Versions in File

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Action Options (NEW)
Direct links to Protocols

Dear Dr. Principal Investigator,

Your animal use protocol #AUP-17-212 has been reviewed by IACUC members and staff. Additional clarifications or revisions are needed:

Respond to Pre-review:
- Please click here to open the protocol
- Click the Check-Out button - This will allow you to edit the protocol
- Click the Review button
- In the Review window, scroll down to the All tab - This will display all review comments/questions
- Respond to all issues and revise the protocol sections in RMS to reflect/incorporate your responses (if applicable)

NOTES:

Questions regarding animal use protocols and training requirements should be directed to IACUC@uci.edu.

To access the Research Management System (RMS), please visit https://rms.research.uci.edu/

Technical support questions? Contact the RMS Help Desk at 949-824-2142 or email: rms-support@uci.edu

Link
Questions? Comments? Feedback?

Martin Nakatsu: mnakatsu@uci.edu or rms-support@uci.edu
Phone: (949) 824-2142
Group Poll
Any final questions or comments?
See you next time...

Spring QRAM

March 28, 2018
1:30pm - 3:30pm
Doheney Beach B