Welcome

Marcia Smith
Associate Vice Chancellor for Research
Agenda

- **Welcome and Announcements** - *Marcia Smith*
  - Response to OMB Call for Ideas on Reducing Compliance Burden Relating to Grants & Contracts

- **FY 2015 Proposal & Award Numbers** - *Rory Constancio & Patti Manheim*

- **Research Policy and Compliance** - *Claudia Modlin & Ann Pollack*
  - Export Control Update
  - Who Owns the Data?

- **OHRPP** - *Kip Kantelo*
  - Release of Federal Notice of Proposed Rule Making

- **OARO** - *Jennifer Perkins*
  - Safety Updates

- **OCGA** - *Heather Winters & Evan Garcia*
  - NASA Indemnification Clause
OMB Call for Ideas on Reducing Compliance Burden Relating to Grants and Contracts
Vote for Reduced Compliance Burden

- OMB initiated effort to collect feedback from colleges and universities
- “National Dialogue and Pilot to Reduce Reporting Compliance Costs for Federal Contractors and Grantees”
- AAU, COGR and APLU recently submitted comments under link for Grantees
- We are encouraged to vote for and comment on ideas submitted and submit new ideas addressing duplicative and/or unnecessary reporting burden
Example Recommendations

- Require Federal agencies to use a Uniform System for proposal submission and award management
- Consolidate Federal Payment Systems
- Require all Federal agencies to adopt common research terms and conditions
- Clarify Uniform Guidance rules on subrecipient monitoring
- Raise micropurchase threshold from $3,000 to $10,000
Link for Grantees

• https://cxo.dialogue2.cao.gov/a/ideas/top/campaign-filter/byids/campaigns/13162
Review ORA FY 2015 Research Proposals & Awards

http://portal.research.ucla.edu/

Rory Constancio
Director, Office of Research Data Management
### Fiscal Year 2015 Final

**Proposal Requested Dollars & Counts**

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<thead>
<tr>
<th>Requested Dollars</th>
<th>Proposal Counts</th>
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<td>$3,815,359,119</td>
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**Awarded Dollars & Counts**

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### Fiscal Year 2015
Comparison to FY 2014

Proposal Requested Dollars & Counts

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## Fiscal Year 2015 Comparison to FY 2014

### Awarded Dollars & Counts

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Awarded Dollars by Sponsor Type
FY 2014 & FY 2015
Export Controls Update

Claudia Modlin
Research Policy & Compliance Coordinator

September 10, 2015
Travel to Cuba

• Since the last update in February 2015, a number of things have changed.
  1. Cuba is no longer considered a State Sponsor of Terrorism.
  2. Diplomatic relations between the US and Cuba were reestablished on July 20, 2015.

• However, to visit Cuba, an individual must either fall within the 12 categories of authorized travel (the general license) OR obtain a specific license (case-by-case determination that requires submitting an application to the Office of Foreign Assets Control (OFAC)).

• The authorization also allows for some travel related transactions that previously required a specific license.

• OFAC has published FAQs about this at: http://www.treasury.gov/resource-center/sanctions/Programs/Documents/cuba_faqs_new.pdf
12 Categories of Authorized Travel:

1. family visits
2. official business of the U.S. government, foreign governments, and certain intergovernmental organizations
3. journalistic activity
4. professional research and professional meetings
5. educational activities
6. religious activities
7. public performances, clinics, workshops, athletic and other competitions, and exhibitions
8. support for the Cuban people
9. humanitarian projects
10. activities of private foundations or research or educational institutes
11. exportation, importation, or transmission of information or information materials
Iran Update

• At a recent university export control meeting in Washington DC, an OFAC official publicly stated that an OFAC license IS required for faculty attending and/or presenting at conferences in Iran.

• Conference attendees/presenters may be considered to be receiving and/or providing a “service.” These “services” may require licensing under the Iranian Transactions Regulations (31 C.F.R. Part 560).

• The need for a license will be determined on a case-by-case basis. Note that OFAC takes a very long time to process these requests.
Data

Ann Pollack
Assistant Vice Chancellor – Research

September 10, 2015
What is Research Data?

- Recorded information that reflects original observations and methods related to a research study.

- The format doesn’t matter.

- Research data does not include administrative records such as financial, personnel/payroll or purchasing records.
Who Owns the Data?

- Per UC Policy, University of California Regulation No. 4 (APM-020), provides that original records of the research are the property of the University.

- NIH Grants Policy and NSF policy give grantees data ownership rights.

- Ownership and Access are not synonymous.
Why Keep Data?

• Accurate and appropriately recorded research data, enable scholars to report, replicate, and refute research findings, which ultimately advances the research enterprise.

• University access to records of research is critical for oversight purposes, such as responding to audits, establishing that past use of University or research sponsor funds was appropriate, responding to government demands or subpoenas, defending research findings, facilitating research misconduct proceedings, and facilitating proper conduct of research with humans or animals.

• In most research contracts and grants, the University has committed to the sponsor that it will retain research data and make it available as appropriate.
Responsibilities

- The Principal Investigator is responsible for ensuring that Research Data are recorded, stored, and used in accordance within the standards of his or her respective discipline, campus department, and any requirements of applicable federal or state law or regulations, University policies and guidelines, and University contractual commitments.

- In general, Principal Investigators shall retain all research data on behalf of the University for as long as possible, but not less than a minimum of six years after final reporting, publication, completion or abandonment of the project, unless a longer retention period is indicated by the funding source or other relevant agreement.
Guidance and Policy

  - Considered a discussion draft
  - Comments encouraged
  - Academic Senate input and other reviews will be solicited before Guidance is finalized
  - [http://ora.research.ucla.edu/Lists/Announcements/Attachments/300/BruinPost_re_UCLA_Interim_Guidance.pdf](http://ora.research.ucla.edu/Lists/Announcements/Attachments/300/BruinPost_re_UCLA_Interim_Guidance.pdf)

- **Draft** UC Policy on Access to and Management of Research Data and Tangible Research Materials – will soon be ready for review.
webIRB Updates

Kip Kantelo, Director
September 10, 2015
Landscape

- Federal, state, institutional
- Federal
  - Common Rule
  - FDA
- 2011 ANPRM
- 2015 NPRM
- 2016(?) Final Notice
NPRM

❖ Goals
• Improve subject protection
• Facilitate research
• Reduce burden
• Reduce delay
• Reduce ambiguity
NPRM

Key Areas

- Meaningful consent
  - Tighten content requirements
  - Public posting
- Consent for secondary use
  - Specimens
  - Data
- Calibrate level of review with risk
  - Rejiggering levels of review
    - Self-certification
  - Continuing Review
NPRM

Key Areas (ctd)

- Single IRB Review for Multi-Site
- Reduce waivers of consent
- Expand scope
  - Clinical trials regardless of funding
NPRM

- OHRPP Analysis
- Invitation to Research Community
  - PIs might also hear from professional societies
- UC coordinated comment
  - Also via societies
Thank you!

❖ For questions:
  • North & South General IRBs
    ❑ x57122
    ❑ gcirb@research.ucla.edu
  • Medical IRBs
    ❑ x55344
    ❑ mirb@research.ucla.edu
OARO: SAFETY UPDATES

Jennifer Perkins, MA, CPIA
Director – Animal Research Oversight
IBC Online System

• Institutional Biosafety Committee (IBC) oversees research and teaching activities involving:
  • Recombinant/synthetic nucleic acid molecules
  • Infectious agents
  • Select agents and select toxins
  • Human and nonhuman primate materials
  • Genetically-modified animals and whole plants
  • Animals known to be reservoirs/vectors of zoonotic diseases

• Online system to replace current “paper-based” submission and review system.
IBC Online System

• The IBC online system has been branded SafetyNet.

• System training occurred the week of August 31 and will continue on a regular basis.

• Anticipated soft launch on September 24, 2015.
IBC Online System

- Researchers due to renew existing approvals will submit a new BUA through SafetyNet.

- ORA will migrate high level information for approved protocols into SafetyNet at or shortly after soft launch.
  - Most current version of approved protocol and SOPs will be loaded into system as attachments.
  - Will require completion of full application at the time of amendment.
http://safetynettettest.research.ucla.edu
Dual Use Research of Concern

• 2011 research on the genetic basis of the transmissibility of H5N1 resulted in the creation of laboratory modified H5N1 viruses capable of respiratory transmission between ferrets; these findings raised a number of issues regarding potential “dual use” research.

• What is DURC?
  • Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.
  • “Good science put to bad uses.”
Dual Use Research of Concern

- March 2012: USG Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC)
  - Sets forth a process of regular Federal review of USG-funded or USG-conducted research and requires Federal agencies that fund or sponsor life sciences research to identify DURC and evaluate this research for possible risks, as well as benefits, and to ensure that risks are appropriately managed and benefits realized.

- September 2014 USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)
  - Establishes review procedures and oversight requirements for the same scope of research at institutions that receive Federal funds for life sciences research.
  - Effective September 24, 2015
Dual Use Research of Concern

• The USG has limited the scope of both Policies to a well-defined subset of life sciences research that involves 15 agents and toxins and seven categories of experiments.

• The September 2014 Policy requires that institutions meet the following requirements:
  • Have policies and practices in place that enable PIs to identify and refer to an Institutional Review Entity (IRE) any life sciences research that requires institutional review.
  • Establish an IRE to execute the institutional review of research for DURC potential.
  • Have policies and practices in place for institutional review and oversight of research.
Dual Use Research of Concern

Agents and toxins
- Avian influenza virus (highly pathogenic)
- Bacillus anthracis
- Botulinum neurotoxin
- Burkholderia mallei
- Burkholderia pseudomallei
- Ebola virus
- Foot-and-mouth disease virus
- Francisella tularensis
- Marburg virus
- Reconstructed 1918 Influenza virus
- Rinderpest virus
- Toxin-producing strains of Clostridium botulinum
- Variola major virus
- Variola minor virus
- Yersinia pestis
Dual Use Research of Concern

Categories of experiments
- Enhances the harmful consequences of the agent or toxin
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
- Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- Alters the host range or tropism of the agent or toxin
- Enhances the susceptibility of a host population to the agent or toxin
- Generates or reconstitutes an eradicated or extinct agent or toxin listed above
Dual Use Research of Concern

Where are we?
- Working with UCOP to finalize a system-wide Policy.
- Establishing the UCLA Dual Use Review Entity (DURE).
- Identifying the UCLA Institutional Contact for Dual Use Research (ICDUR).
- Drafting DURE charter.

What’s coming?
- ORA will contact PIs already using any of the 15 agents.
- Assessment of existing research for dual use potential.
Questions?

• ARC Questions
  • oaro@research.ucla.edu
  • 310-206-6308

• IBC Questions
  • oibc@research.ucla.edu
  • 310-206-3182

• Me (DURE Questions)
  • jperkins@research.ucla.edu
  • 310-794-9645
NASA 1800.918
Allocation of Risk/Liability
Heather Winters
Assistant Director
heather.winters@research.ucla.edu

Evan Garcia
Senior Grant Analyst
egarcia@research.ucla.edu
NASA 1800.918
Allocation of Risk/Liability

NASA has applied a new condition ("Allocation of Risk/Liability" (CFR 1800.918) to all new and amended grants and cooperative agreements that previously only affected foreign organizations.
NASA 1800.918
Allocation of Risk/Liability

• a) With respect to activities undertaken under this agreement, the Recipient agrees not to make any claim against NASA or the U.S. Government with respect to the injury or death of its employees or its contractors and subcontractor employees, or to the loss of its property or that of its Contractors and subcontractors, whether such injury, death, damage or loss arises through negligence or otherwise, except in the case of willful misconduct.
NASA 1800.918
Allocation of Risk/Liability

(b) In addition, the Recipient agrees to indemnify and hold the U.S. Government and its Contractors and subcontractors harmless from any third party claim, judgment, or cost arising from the injury to or death of any person, or for damage to or loss of any property, arising as a result of its possession or use of any U.S. Government property.

(end of clause)
NASA 1800.918
Allocation of Risk/Liability

UCOP has determined Section (b) of the clause may involve indemnification for the actions of 3rd parties, and falls outside of Standing Order 100.4(dd).

UCOP has developed guidance on assessing the liabilities and risks under each project in order to ascertain the potential financial and legal risks involved to reduce or eliminate any such financial/legal risks.
NASA 1800.918
Allocation of Risk/Liability

UCLA is developing a campus process congruent with UCOP guidance which will include:

- Coordination with Risk Management and other applicable offices
- A checklist to identify the level of risk for the specific project
- PI/Chair/Dean informed consent
Questions?