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.
IBC Online System

http://safetynettest.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