

# The Institutional Biosafety Committee

Presented by:

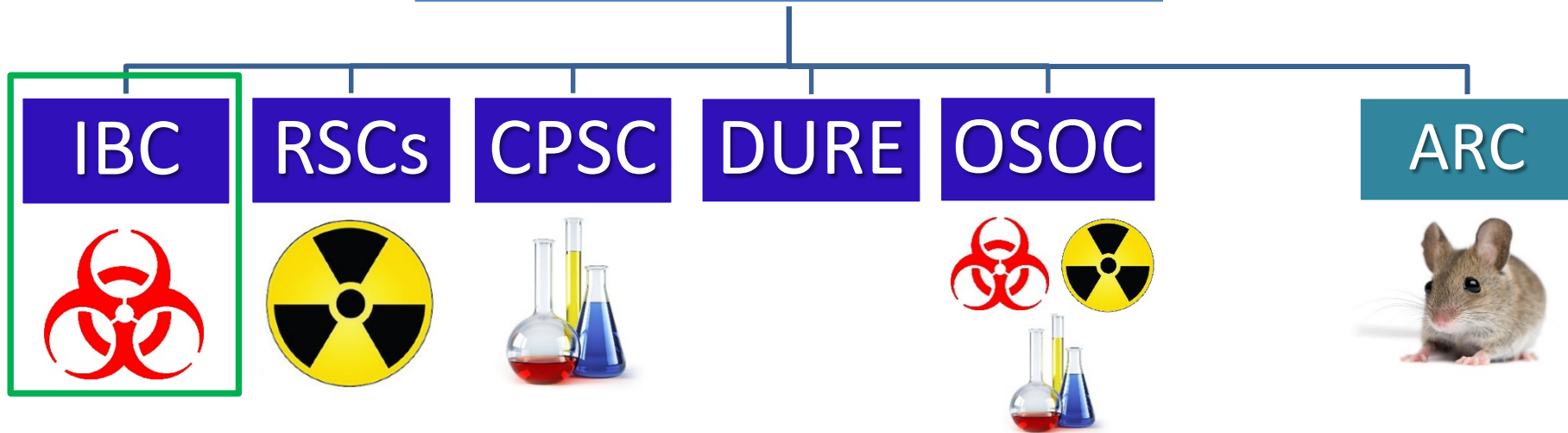
Alyse DiStefano, IBC Manager

March 8, 2018



# RSAWA Compliance Committees

ORA Research Safety and  
Animal Welfare  
Administration



## Office of the Vice Chancellor for Research

IBC Member Appointments



## Office of Research Administration (ORA)



### IBC Administrative Office

- All administrative support for the IBC
- Regulatory compliance issues
- Incident and non-compliance reporting to NIH
- Annual reporting to NIH
- Policies
- Education and outreach on IBC issues

## Office of the Vice Chancellor of Administration



## Environment, Health & Safety (EH&S)



### EH&S Biosafety Program

- Expertise on biosafety issues
- Incident Investigation
- Biosafety inspections and training
- Facility design consultations
- Emergency response
- Medical Waste Management Program
- Select Agent and Toxin Program
- BSL3 Program
- Primary contact for regulatory agencies



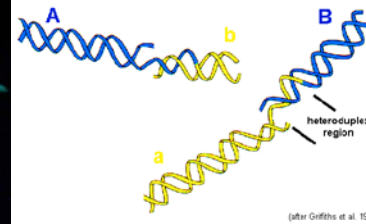
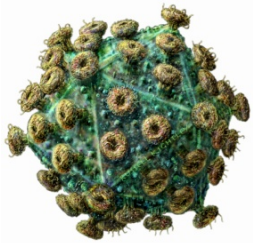
# The Institutional Biosafety Committee (IBC)

- ❑ Mandated by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*
- ❑ Faculty-led committee appointed by the Vice Chancellor for Research
- ❑ Reviews **Biological Use Authorization (BUA)** applications
- ❑ Experts in various fields including plant containment, animal containment, clinical trials, infectious disease, field research

# Scope of UCLA's IBC

Academic research and teaching operations using the following materials:

- Recombinant and 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



# IBC Risk Assessment Process

The IBC considers the following items when performing a biological risk assessment:

- PI Expertise
- Proposed Biosafety Level
- Proposed Locations
- Engineering Controls (e.g., biosafety cabinet, aerosol-tight devices)
- Biosafety Practices
- Risk of Environmental Release
- Standard Operating Procedures (SOPs)
- Personnel Training (e.g., EH&S, lab-specific)
- Hazard Communication
- Occupational Health Considerations (e.g., vaccinations, medical surveillance)



# Standard Conditions of Approval

## ✓ Completion of Training by All Personnel

Visit <https://Worksafe.ucla.edu> to sign up for in-person trainings or to complete online trainings.

## ✓ Satisfactory EH&S Biosafety Review (Inspection)

- Review of procedures/operations
- Review of facilities
- Review of biosafety manual

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## ✓ Ancillary Approvals (ARC, IRB, ESCRO, etc.)

# NIH Grants Policy Statement

## 4.1.12 Health and Safety Regulations and Guidelines

Recipients are responsible for meeting applicable Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- 29 CFR 1910.1030, Blood borne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR 1910. These regulations are available at [http://www.osha.gov/pls/oshaweb/owastand.display\\_standard\\_group?p\\_toc\\_level=1&p\\_part\\_number=1910](http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910).

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Recipient organizations are not required to submit documented assurance of their compliance with or implementation of these regulations and guidelines. However, if requested by the awarding IC, recipients should be able to provide evidence that applicable Federal, State, and local health and safety standards have been considered and have been put into practice. |

# NIH Grants Policy Statement

## 4.1.26 Research Involving Recombinant or Synthetic Nucleic Acid Molecules (including Human Gene Transfer Research)

### 4.1.26.1 Scope and Availability

*The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* (April 2016 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research. A copy of the *NIH Guidelines* is available at <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>

According to the *NIH Guidelines*, recombinant and synthetic nucleic acid molecules are defined as (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The *NIH Guidelines* apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the *NIH Guidelines*.

Failure to comply with these requirements may result in suspension or termination of an award for recombinant or synthetic nucleic acid molecule research at the organization, or a requirement for NIH prior approval of any or all recombinant or synthetic nucleic acid molecule projects at the organization. Two specific requirements of the *NIH Guidelines* are discussed below, but the recipient should carefully review the *NIH Guidelines* in their entirety to ensure compliance with all of the requirements for projects involving recombinant or synthetic nucleic acid molecules.

Recombinant or synthetic nucleic acid research involving select agents also is subject to pertinent CDC and USDA regulations, 42 CFR 73, Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121, Possession, Use, and Transfer of Biological Agents and Toxins.

# NIH Grants Policy Statement

## **4.1.24.1 Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents)**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. 201, is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the U.S. homeland or other criminal acts. The Act was implemented, in part, through regulations published by HHS and USDA at 42 CFR 73, 9 CFR 121 and 7 CFR 331 or commonly referred to as "Select Agent Regulations." Copies of these regulations are available at <http://www.selectagents.gov/Regulations.html>, or can be obtained from CDC, 1600 Clifton Road, MS A-46, Atlanta, GA 30333; telephone: 404-718-2000.

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### **4.1.24.1.1 Select Agents**

#### **4.1.24.1.1.1 Select Agent Awards to U.S. Institutions**

Domestic recipients who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR 73 and 9 CFR 121 and Section 3 of 7 CFR 331) must maintain a registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.

# EPASS

- Does this proposal involve the use of significant IT resources (beyond basic academic infrastructure); the generation of datasets or digital assets; or a budget with over \$10,000 in IT-related hardware, software, or staff expenditures? (Check [additional requirements](#))
- Human Subjects? If yes, indicate "Pending", IRB # or Exemption #: \_\_\_\_\_ Delayed Onset
- NIH-funded Clinical Trial? If yes, investigators and staff involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice. Training is available through [CITI Program](#). Provide names on the next page.
- Will the clinical research study utilize UCLA Health System resources, including but not limited to, any patient care costs? If yes, then a Policy 915 Coverage Analysis is required (contact [coverageanalysis@mednet.ucla.edu](mailto:coverageanalysis@mednet.ucla.edu)).
- Animal Subjects? If yes, indicate "Pending" or ARC#: \_\_\_\_\_ Delayed Onset
- Human Embryonic Stem Cell Research? If yes, refer to the [Stem Cell Policy and Procedures](#).
- Non-UCLA materials/equipment to be used? If yes, indicate type: \_\_\_\_\_ Source: \_\_\_\_\_
- Human or primate cells, tissue, or fluids; recombinant or synthetic nucleic acids; potentially infectious materials; exotic plants or plant pathogens; select agents or toxins? For more information, see [IBC website](#).
- Use of UC IP? If yes, specify case number: \_\_\_\_\_

# SafetyNet

<http://safetynet.research.ucla.edu/>



**SafetyNet**

UCLA Research Administration  
IBC Online System

Login

Home

Home

- ▷ **Login**
- ▷ **How to Access the System**
- ▷ **Quick Reference Guides & Training Materials**
- ▷ **Contact Us**

## Welcome to IBC

**Bookmark:** Bookmark the above URL for easy access. In your browser, go to

*Favorites → Add To Favorites or Bookmarks → Bookmark This Page*

**Logon:** When prompted, log in using your UCLA Logon ID (formerly Bruin Online account). If you have forgotten your logon ID or need to reset your password, visit <http://logon.ucla.edu>

### IBC Help Desk

Phone Number: 310-794-0262  
Hours: 8am – 5pm, Monday – Friday  
[oibc@research.ucla.edu](mailto:oibc@research.ucla.edu)

# The UCLA Institutional Biosafety Plan

<https://ucla.app.box.com/v/UCLA-Biosafety-Plan>



# Contact Information

[ibc@research.ucla.edu](mailto:ibc@research.ucla.edu)

**310-794-0262**

<http://ora.research.ucla.edu/RSAWA/IBC>