

## PPM 482: Control of Biohazards and Biological Materials in Research

<b>Responsible Officer:</b>	Director, Risk and Safety Services
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### TABLE OF CONTENTS

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I.	POLICY SUMMARY .....	2
II.	DEFINITIONS .....	2
III.	POLICY TEXT .....	2
IV.	COMPLIANCE / RESPONSIBILITIES .....	3
V.	PROCEDURES .....	4
VI.	RELATED INFORMATION .....	4
VII.	FREQUENTLY ASKED QUESTIONS.....	4
VIII.	REVISION HISTORY .....	4

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## I. POLICY SUMMARY

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Biohazards are microorganisms, including recombinant DNA (rDNA) molecules, which are commonly accepted as having the potential to pose a hazard to human and/or animal health or the environment. Biohazards used in research include pathogenic bacteria, fungi, parasites, protozoans, viruses, oncogenic viruses, rDNA, and plant and animal toxins. University of California (UC) practices regarding research using biohazards are discussed in the UCOP Research Administration Office Contract and Grant Manual [Sections 3-400 through 3-460](#).

The National Institutes of Health (NIH) has issued guidelines to specify practices for constructing and handling rDNA molecules and organisms and viruses containing rDNA molecules. Among other requirements, the [NIH guidelines](#) specify that an institution performing research with rDNA molecules shall:

1. Establish and implement policies that provide for the safe conduct of rDNA research and that ensure compliance with the NIH Guidelines.
2. Establish an Institutional Biosafety Committee (IBC).
3. Appoint a Biological Safety Officer.

NIH and the Centers for Disease Control (CDC) also have described safety practices that should be used when conducting research that involves biohazardous or infectious agents. These practices are summarized in the booklet "[Biosafety in Biomedical and Microbiological Laboratories](#)." This booklet describes laboratory practices, safety equipment, facility design and four biosafety levels.

Each UC campus and national laboratory that is performing research using biohazardous materials has established an IBC to implement these requirements. The IBC reviews potential projects and issues Biological Use Authorizations (BUA) to ensure biohazardous work is conducted in compliance with applicable regulations and NIH guidelines. The BUA will describe the material(s) to be used and include a description of the research protocol, necessary control measures and safety equipment, decontamination procedures, waste management, training requirements, record keeping and inspection requirements.

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## II. DEFINITIONS

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## III. POLICY TEXT

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### **Storage, Use Or Research Of Biological Materials**

Any storage, use, or research of biological materials that requires Biosafety Level 2 or higher level of protection is prohibited at UC Agriculture and Natural Resources (ANR) facilities or at other facilities while under an ANR employee's custody and control, unless the Principal Investigator first obtains approval (in the form of a BUA) from a campus IBC. If campus IBC review is not appropriate, contact the ANR Environmental Health & Safety office (see contact information above). A copy of the BUA shall be kept on file at the ANR facility where the research occurs. Experiments involving biological materials

that do not present a significant risk to health or the environment are exempt from the requirements of the NIH guidelines.

### **Transfer Or Transport Of Biological Materials**

The transfer or transport of plants, plant pests, animals, animal material, etiologic agents, or genetically modified organisms is regulated by federal agencies such as the US Department of Agriculture (USDA) – Animal and Plant Health Inspection Service (APHIS), US Fish and Wildlife Service, and the CDC. State agencies such as the California Department of Food and Agriculture, Division of Plant Health and Pest Prevention Services, and Department of Fish and Game also regulate the transport and possession of plants, plant pests and animals. Some local governments may have additional requirements.

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## **IV. COMPLIANCE / RESPONSIBILITIES**

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**A.** ANR employees shall make themselves aware of the regulations relating to biological materials they may consider using, bringing into the United States, moving between states, or moving from one location to another within the state. These regulations include, but are not limited to:

1. Federal

- a. 7 CFR (Agriculture), Subtitle B, Chapter 3 – Animal and Plant Health Inspection Service, Parts 300-380
- b. 9 CFR (Animals and Animal Products), Chapter 1, Subchapter C--Interstate Transportation of Animals (Including Poultry) and Animal Products, Parts 70-89
- c. 9 CFR (Animals and Animal Products), Chapter 1, Subchapter D--Exportation and Importation of Animals (Including Poultry) And Animal Products, Parts 91-99
- d. 42 CFR (Public Health), Chapter 1, Subchapter F-- Quarantine, Inspection, Licensing, Parts 70-75
- e. 49 CFR (Transportation), Subchapter C--Hazardous Materials Regulations, Parts 171-180
- f. 50 CFR (Wildlife and Fisheries)

2. State

- a. CA Code of Regulations (CCR), Title 3 (Food and Agriculture), Division 4
- b. CA Fish and Game Code Section 1002 and CCR Title 14 Sections 650 and 670.7

**B.** Over and above any precautions stated in legal terms in this policy, each staff member shall not to bring into the United States or the State of California any living material not allowed under current regulations.

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## V. PROCEDURES

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## VI. RELATED INFORMATION

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### University Of California

- UC Office Of The President, Research Administration Office, Contract And Grant Manual [University Policy On Biohazards And Recombinant DNA](#)
- Agriculture And Natural Resources, [Environmental Health & Safety Website](#)

### Federal Agencies

- National Institutes Of Health, Recombinant DNA And Gene Transfer [Guidelines For Research Involving Recombinant DNA Molecules](#)
- U.S. Department Of Health And Human Services, [Centers For Disease Control And Prevention And National Institutes Of Health Biosafety In Biomedical And Microbiological Laboratories](#)
- USDA Animal And Plant Health Inspection Service [Import-Export Library](#)
- U.S. Department Of Health And Human Services, Centers For Disease Control And Prevention, Office Of Health And Safety [Etiologic Agent Import Permit Program](#)
- National Institutes Of Health [Biosafety In Biomedical And Microbiological Laboratories](#), Appendix C, Transportation And Transfer Of Biological Agents
- US Fish & Wildlife Service [Permits Overview](#)

### State Agencies

- California Department Of Food And Agriculture, Division Of Plant Health And Pest Prevention Services [Permits And Regulations Program](#)
- California Department Of Fish And Game, Habitat Conservation Planning Branch [Environmental Review And Species Take Permits](#)
- California Department Of Fish & Game, License And Revenue Branch [Special Permits Information](#)

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## VII. FREQUENTLY ASKED QUESTIONS

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## VIII. REVISION HISTORY

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Format updated.