

## **24.01.01.R0.02 Infectious Biohazards and/or rDNA in Research**

Approved July 12, 2010



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### **Procedure Statement**

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All research in which rDNA and/or infectious biohazards are involved (including on humans and plants) performed under the auspices of Texas A&M University-Commerce, including cooperative research conducted with one or more public or private entities, must be reviewed and approved by the Institutional Biosafety Committee (IBC).

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### **Reason for Procedure**

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Texas A&M University-Commerce complies with regulations of the National Institutes of Health (NIH) for the use of rDNA and/or infectious biohazards in research. These regulations, as defined by NIH, are applicable to **all** research (including humans and plants) involving the use of rDNA and/or infectious biohazards for which the university is responsible, regardless of the source of funding or whether the research is funded or not funded. In the case of conflict between regulations of the funding or regulatory agency and NIH, the more restrictive regulations shall prevail.

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### **Procedures and Responsibilities**

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#### **1. INSTITUTIONAL BIOSAFETY COMMITTEE**

1.1 The president of the university, in consultation with the dean of graduate studies and research, will appoint members to staggered three-year terms to the Institutional Biosafety Committee (IBC). The IBC chair will be granted appropriate release time to carry out the responsibilities.

1.2 All members of the IBC will complete all appropriate training applicable to biosafety.

#### **2. INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW AND APPROVAL**

2.1 The IBC's review and approval process shall be conducted in accordance with all Federal, State, System, and University rules, policies, regulations, and laws that govern the use of rDNA and/or infectious biohazards in research (including humans and plants).

The requirement for IBC review and approval applies to all studies in all locations, whether funded or not funded, and whether conducted by faculty, students, or staff. It also applies to persons not affiliated with the university who wish to coordinate research through the university using rDNA and/or infectious biohazards. No such study may begin before it has been approved.

2.2 Texas A&M University-Commerce shall comply with the ethical principles, considerations, and concerns, as outlined in the NIH guidelines for research (including humans and plants) involving rDNA and/or infectious biohazards.

2.3 The IBC will review research at intervals appropriate to the degree of risk, but not less than once per year. This review shall include, but is not limited to: (i) independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research.

### 3. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

3.1 Principal investigators and unit heads are responsible for assuring that rDNA and/or infectious biohazards research (including humans and plants) is appropriately reviewed and approved by the IBC prior to the initiation of any work. Regardless of funding sources, research protocols involving the use of rDNA and/or infectious biohazards in teaching and research must be prepared by the principal investigator and must be reviewed by the IBC. In addition, written approval must be obtained from the IBC prior to making changes in the rDNA and/or infectious biohazards protocols. If research is collaborative or involves other institutions, approval must be obtained from each institution. Approval to use rDNA and/or infectious biohazards in animals or humans must be approved by the applicable research committees.

3.2 The principal investigator is responsible for ensuring that the laboratory staff are appropriately trained, including completion of all university training modules applicable to biosafety.

3.3 It is the responsibility of the principal investigator and department head to ensure compliance with all Federal regulations involving the handling, storage, disposal, inventory, security, or access to biological, chemical, and/or radiological agents. The Department of Risk Management and Safety shall assist in this process.

### 4. OTHER

4.1 All documentation associated with IBC reviews will be maintained within the Office of Sponsored Programs. Sufficient resources will be provided to support the IBC in all phases of its work, help track and monitor submissions, and maintain records related to all research involving rDNA and/or infectious biohazards. The Office of Sponsored Programs will be responsible for determining that applicable theses and dissertations have received approval by the IBC.

4.2 All individuals involved with rDNA and/or infectious biohazards in research will complete all appropriate training, including all university prescribed training modules applicable to biosafety.

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## **Related Statutes, Policies, or Requirements**

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System Policy [24.01.01 Supplemental Risk Management Standards](#)  
[NIH Guidelines for Research Involving Recombinant DNA Molecules \(NIH Guidelines\)](#)

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## **Contact Office**

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