Policies of the University of North Texas at Dallas	Chapter 15
15.009 Biosafety	**Risk Management Services**

Policy Statement. This policy establishes responsibility for the proper use of biohazardous agents, potentially hazardous human materials, and recombinant DNA molecules in research and other educational activities at the University of North Texas at Dallas (UNTD) in order to protect students, faculty, staff, the community, and the environment.

Application of Policy. Total University.

Definitions.

1. Biohazardous agents. Any microorganism, virus, infectious substance, or toxin that is biological in nature and capable of producing deleterious effects upon humans, animals, plants, or the environment.
2. Human materials. Human blood, blood components, blood products, body fluids, tissues, or organs.
3. Principal Investigator. Any UNTD faculty member, staff employee, or student conducting research or other educational activities utilizing UNTD facilities; or due to his/her status as a UNTD employee or student involving biohazardous agents, potentially hazardous human materials, or recombinant DNA molecules.
4. Recombinant DNA. (1) Molecules that are constructed by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) molecules that result from the replication of those described in (1).

Procedures and Responsibilities.

I. Institutional Policy. It is the policy of the University that all Principal Investigators shall assume primary responsibility for the proper use, handling, and disposal of all biohazardous agents, potentially hazardous human materials, and recombinant DNA molecules in research or other educational activities conducted utilizing UNTD facilities or due to their status as a UNTD employee or student. For any research or educational use of biohazardous agents, human materials, or recombinant DNA molecules, UNTD requires compliance with Biosafety in Microbiological and Biomedical Laboratories, the NIH Guidelines for Research Involving Recombinant DNA Molecules, the OSHA Occupational Exposure to Bloodborne Pathogens Standard, and any guidelines adopted by the UNTD Institutional Biosafety Committee (IBC). To protect students, faculty, staff, the community, and the environment, the IBC is authorized to review and monitor all research and other educational activities involving biohazardous agents, potentially hazardous human materials, and recombinant DNA molecules, whether such research is funded or

not. Failure to comply with this policy will result in an additional review by the IBC and possible suspension or revocation of approval by the IBC to work with biohazardous agents, potentially hazardous human materials, and recombinant DNA molecules; and may result in disciplinary action under the procedures applicable to faculty, staff, and students.

II. Institutional Biosafety Committee. IBC Responsibilities. The Institutional Biosafety Committee (IBC) reviews and monitors all research projects and educational activities involving the use of biohazardous agents, potentially hazardous human materials, and recombinant DNA molecules. Responsibilities of the IBC shall include the following:

A. assessing the containment levels required by the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines);

B. assessment of the facilities, procedures, practices, and training and expertise of personnel involved in research or other educational activities;

C. notifying the Principal Investigators, laboratory directors, the Office of Sponsored Projects , and other appropriate UNTD committees of the results of the IBC's review of initial and renewal applications;

D. by adopting emergency plans covering accidental spills and personnel contamination resulting from research or other educational activities, the IBC shall cooperate with state and local public health departments by reporting any significant research or education-related illnesses or accidents that may be hazardous to the public health;

E. periodically reviewing biohazardous agents, human materials, and recombinant DNA molecules research or other educational activities conducted at UNTD to ensure compliance with Biosafety in Microbiological and Biomedical Laboratories, the NIH Guidelines, the OSHA Occupational Exposure to Bloodborne Pathogens Standard, and any guidelines adopted by the IBC;

F. reporting any significant problems with or violations of the NIH Guidelines and any significant research/education related accidents or illnesses involving recombinant DNA molecules to the UNTD Provost and Executive Vice President for Academic Affairs and the NIH Office of Biotechnology Activities within 30 days, unless the IBC Chair determines that a report has already been filed by the Principal Investigator;

G. filing an annual report, if applicable, with the NIH Office of Biotechnology Activities; and

H. annually reviewing this policy and recommending any revisions needed to the Provost and Executive Vice President for Academic Affairs and UNTD Policy Committee.

I. developing emergency plans for handling and investigating laboratory accidents

involving biohazardous agents, human materials, or recombinant DNA molecules;

J. working with RMS to provide technical advice on research safety and laboratory security procedures to Principal Investigators, laboratory personnel, and students;

K. The IBC Chair serves as a liaison between UNTD and external regulatory agencies concerned with the use of biohazardous agents, human materials, and recombinant DNA molecules; and

L. The IBC shall maintain records containing the following information:

- a copy of each application or renewal form describing the proposed research project or educational activity;
- a copy of the minutes of each IBC meeting, including deliberations and actions on new projects reviewed, and the renewal, modification, or termination of projects previously approved; and
- copies of reports and correspondence with the NIH (if applicable), including any relating to problems, accidents, illnesses, or violations of the NIH Guidelines.

Responsible Party: IBC and IBC Chair

IBC Membership. The IBC shall consist of at least four voting members, plus ex-officio members. A representative from the Risk Management Services (RMS) and a representative from the Office of Sponsored Projects shall serve as ex-officio non-voting members of the IBC. The UNTD Provost and Executive Vice President for Academic Affairs shall appoint the IBC members and shall designate one voting member as the Chair of the IBC. The Chair shall vote only in the event of a tie vote. At least one individual with no affiliation to UNTD shall be appointed to represent the local community. The term for each member shall be three years with staggered terms, and members shall be eligible for re- appointment. Members shall be selected so that they collectively have the expertise and experience to review the types of biohazardous agents, potentially hazardous human materials, and recombinant DNA molecules research and other educational activities conducted at UNTD to assess the safety of such research and to identify any potential risk to public health or the environment. The IBC shall meet as needed, but at least once per year. An IBC member shall be disqualified from review of a proposal or activity in which he or she expects to be engaged or has a significant financial interest, except to provide information requested by the IBC. The IBC may use non-voting ad hoc consultants as necessary to provide special expertise for review of specific proposed research or educational projects.

Responsible Party: Provost and Executive Vice President for Academic

Affairs, RMS, IBC Chair

III. Principal Investigator (PI) or Lab Manager. The responsibilities of the Principal Investigator shall include the following (for teaching labs, the Lab Manager shall be responsible for these duties):

A. instructing and training laboratory staff in the practices and techniques required to ensure safety and proper emergency response and notification procedures in the event of an accident or injury. The Principal Investigator must also familiarize his/her staff with the symptoms of exposure and other pertinent information about the biohazardous agents, human materials, or recombinant DNA molecules used in the research or educational activity before allowing laboratory personnel to work with such materials;

B. supervising the laboratory staff's safety performance to ensure that the required safety practices and techniques are continuously employed;

C. informing the laboratory staff of the reasons for any precautionary medical practices advised or requested, such as immunization or serum collection;

D. selecting and providing personal protective equipment to all laboratory staff members based on the procedures used in the laboratory;

E. maintaining written documentation for all training activities, which includes instruction in laboratory safety procedures, for all laboratory staff personnel;

F. having the laboratories annually inspected when biohazardous agents, human materials, or recombinant DNA are used for research or other educational activities to ensure that laboratory standards are being followed;

G. investigating and reporting in writing to the IBC and RMS any significant problems or incidents pertaining to the operation and implementation of containment practices and procedures; and

H. complying with all applicable federal, state, and IBC regulatory requirements and with the specifications of the approved research or educational activity.

Responsible Party: Principal Investigator. In the case of this being a teaching lab, then this section of the policy shall be the responsibility of the Lab Manager, not the Principal Investigator.

IV. Approval of Use of Biohazardous Agents, Potentially Hazardous Human Materials, and Recombinant DNA Molecules

A. Biohazardous Agents. Any proposed research or other educational activity using biohazardous agents must be approved by the IBC prior to acquisition of the agents or initiation of the activity.

The NIH Guidelines for Research Involving Recombinant DNA Molecules, Appendix B ("Classification of Human Etiological Agents on the Basis of Hazard"), lists the most commonly encountered infectious agents by risk group. This list may be

viewed on the National Institutes of Health's Office of Biotechnology Activities website. The Principal Investigator is responsible for reviewing the NIH Guidelines and specifying in the IBC application the appropriate category for the proposed research or educational activity, subject to approval of such classification by the IBC.

B. Human Materials. All proposed research or other educational activities involving the use of potentially hazardous human blood, blood components, blood products, body fluids, tissues, or organs must be approved by the IBC prior to acquisition of the materials or initiation of the activity.

C. Recombinant DNA Molecules. All proposed research or educational activities involving recombinant DNA molecules must be approved by the IBC prior to acquisition of the material or initiation of the activity.

The NIH Guidelines for Research Involving Recombinant DNA Molecules, Section III ("Experiments Covered by the NIH Guidelines"), describes the six categories of experiments involving recombinant DNA molecules. The Principal Investigator is responsible for reviewing the NIH Guidelines on the NIH Office of Biotechnology website and specifying in the application the appropriate category for the activity, subject to approval of such classification by the IBC.

Responsible Party: Principal Investigator, IBC

V. Application Review by the IBC. Upon receipt of an application or renewal form for the use of biohazardous agents, potentially hazardous human materials, or recombinant DNA molecules, the IBC at its discretion may conduct a detailed review of the proposed research or educational activity, including the Principal Investigator's experience, qualifications, research procedures, laboratory facilities, and equipment. Such review may include a personal interview with the Principal Investigator and an inspection of the proposed laboratory facilities.

Application and renewal forms are available on the UNTD IBC website. Completed forms will be submitted to the IBC in accordance with the guidelines on the IBC website. An application will be approved for up to three years and will be reviewed annually on the first and second anniversaries of the original approval date, pending receipt of a renewal form from the Principal Investigator at least six weeks prior to such anniversary dates. After three years, if work under the originally approved application is still continuing, the Principal Investigator must submit a new application for full review and approval by the IBC.

Responsible Party: Principal Investigator, IBC

Use of Animals, Human Subjects, or Radiation. In addition to IBC approval, any research or other educational activity involving biohazardous agents, potentially hazardous human materials, or recombinant DNA molecules in conjunction with the use of animals, human subjects, or radiation also requires approval from the appropriate UNTD committees:

Animals – Institutional Animal Care and Use Committee (IACUC). See UNTD Policy 13.018 *Care and Use of Animals in Research*.

Human Subjects – Institutional Review Board for the Protection of Human Subjects (IRB). See UNTD Policy 13.017 *Protection of Human Subjects in Research*.

Radiation – IBC

Review of proposed research or educational activities by the above committees may run parallel with review by the IBC.

Responsible Party: Principal Investigator, IACUC, IRB, IBC

VI. Termination or Suspension of Research or Other Educational Activity. A Principal Investigator who willfully or negligently violates Federal, state, or UNTD guidelines governing the use of biohazardous agents, potentially hazardous human materials, or recombinant DNA molecules may have his/her IBC approval suspended by the IBC, pending further investigation and final action by the IBC. In the event the IBC's final action includes revocation of IBC approval for the use, the IBC is authorized to notify any sponsoring agency of such action.

Responsible Party: IBC

VII. Procedure for Reporting Violations. Any suspected violation of this policy may be reported to:

A. the UNTD IBC Chair or

B. the UNTD/UNT System Compliance Officer

All such reports will be referred to the IBC for review and, if warranted, an investigation to determine if corrective action is needed.

Responsible Party: IBC Chair, UNTD/UNT System Compliance Officer

References and Cross-references.

- *Biosafety in Microbiological and Biomedical Laboratories*, Centers for Disease Control and Prevention and National Institutes of Health, U.S. Department of Health and Human Services, 5th Edition
- *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*, National Institutes of Health, U.S. Department of Health and Human Services, April 2002.
- *Occupational Exposure to Bloodborne Pathogens Standards*, Occupational Safety and Health Administration, U.S. Department of Labor, 29 C.F.R. 1910.1030.
- National Institutes of Health's Office of Biotechnology Activities website
- Texas Administrative Code
- Laboratory Biorisk Management Standard (CEN Workshop Agreement)
- Dual Use Research of Concern (DURC) Policy

Forms and Tools.

- UNTD Institutional Biosafety Committee (IBC) Website
- **University of North Texas at Dallas Biosafety Manual**
- Registration of Biohazards and Recombinant DNA (with form)
- US DHHS Select Agents Final Regulations
- **IBC Project Registration Form**, including submission instructions
- IBC Application Update Form
- **IBC Registration Exemption Form**
- **IBC Annual Registration Review Form**
- BSL-2 Lab Specific Biosafety Manual Template
- Biohazard Incident Report Form
- Incident Report Form

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