Policies of the University of North Texas	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 (UNT) 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 UNT faculty member, staff employee, or student conducting research or other educational activities utilizing UNT facilities or due to his/her status as a UNT employee or student involving biohazardous agents, potentially hazardous human materials, or recombinant DNA molecules.
4. Recombinant DNA. 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 UNT facilities or due to their status as a UNT employee or student. For any research or educational use of biohazardous agents, human materials, or recombinant DNA molecules, UNT 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 UNT Institutional Biosafety Committee (IBC). To protect students, faculty, staff, the community, and the environment, the IBC and the Biosafety Officer are 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 a 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 Research Services, and other UNT 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 UNT 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 UNT Vice President for Finance and Administration and the NIH Office of Biotechnology Activities within 30 days, unless it is determined that a report has already been filed by the Principal Investigator;

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

H. annually reviewing this policy and recommending any revisions needed to the Vice President for Finance and Administration.

Responsible Party: IBC

IBC Membership. The IBC shall consist of at least six voting members, including the Biosafety Officer. A representative from the Risk Management Services (RMS)

shall serve as ex-officio non-voting members of the IBC. The UNT Vice President for Finance and Administration 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 two individuals with no affiliation with UNT 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 UNT 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: Vice President for Finance and Administration, RMS, IBC Chair

III. Biosafety Officer. The Biosafety Officer shall be appointed by the Vice President for Finance and Administration. The responsibilities of the Biosafety Officer shall include the following:

A. periodically inspecting all laboratories where biohazardous agents, human materials, or recombinant DNA research or other educational activities are being conducted to ensure that laboratory standards are being followed;

B. reporting to the IBC and to the Vice President for Finance and Administration any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the Biosafety Officer becomes aware, unless the Biosafety Officer determines that a report has already been filed by the Principal Investigator;

C. developing emergency plans for handling and investigating laboratory accidents involving biohazardous agents, human materials, or recombinant DNA molecules;

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

E. serving as a liaison between UNT and external regulatory agencies concerned with the use of biohazardous agents, human materials and recombinant DNA molecules; and

F. serving as a voting member of the IBC, including eligibility for appointment as Chair.

Responsible Party: Vice President for Finance and Administration, Biosafety Officer

IV. Principal Investigator. The responsibilities of the Principal Investigator shall include the following:

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. 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

G. 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

V. 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

VI. 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 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 UNT committees:

Animals – Institutional Animal Care and Use Committee (IACUC).

Human Subjects – Institutional Review Board for the Protection of Human Subjects (IRB).

Radiation – Radiation Safety Committee.

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, Radiation Safety Committee

VII. Termination or Suspension of Research or Other Educational Activity. A Principal Investigator who willfully or negligently violates Federal, state, or UNT 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

VIII. Institutional Biosafety Committee Recordkeeping. The IBC shall maintain records containing the following information:

A. a copy of each application or renewal form describing the proposed research project or educational activity;

B. a copy of the minutes of each IBC meeting, including deliberations and actions on new projects reviewed, and renewal, modification or termination of projects previously approved; and

C. copies of reports and correspondence with the NIH, including any relating to problems, accidents, illnesses or violations of the NIH Guidelines.

Responsible Party: IBC

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

A. the UNT Biosafety Officer at the telephone number or e-mail address indicated on the Risk Management Services website; or

B. the UNT Compliance Office at www.unt.edu/compliance.

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: Biosafety Officer, Compliance Office

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, 4 th Edition, May 1999.

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.

Forms and Tools.

Institutional Biosafety Committee

University of North Texas Biosafety Handbook

Registration of Biohazards and Recombinant DNA (with form)

US DHHS Select Agents Final Regs

Effective: 1/2005
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*Format only