Policy Chapter:	**Chapter 15 Risk Management**
Policy Number and Title:	**15.009 Biosafety**

I. Policy Statement

The University of North Texas is committed to planning and implementing control practices for the safe handling of biological materials in its facilities and to protecting the surrounding community and environment. This policy establishes the framework of control practices for the safe handling of biological materials and the appropriate assessment of potential risks at University of North Texas research, clinical and teaching activities. Control practices are based on the applicable regulatory requirements or current safety guidelines, including but not limited to Microbiological and Biomedical Laboratories (current version), the NIH Guidelines for Research Involving Recombinant DNA Molecules (current version), the OSHA and Texas Occupational Exposure to Bloodborne Pathogens Standards, the UNT Biosafety Manual (current version), the Institutional Biosafety Committee (IBC) Charter, and any additional guidelines adopted by the UNT IBC.

II. Application of Policy

All UNT Faculty, Staff, and Students

III. Policy Definitions

A. Biohazardous Agents

"Biohazardous Agents," in this policy, are any microorganism (including, but not limited to, bacteria, chlamydia, and their phages and plasmids, viruses, fungi, mycoplasmas, rickettsia, protozoa, parasites, or prions) or infectious substance, human and non-human derived material, animals and animal derived materials, plants and plant derived materials or any naturally occurring, bioengineered, or synthesized component of any such organism or infectious substance which are capable of causing: death, disease, or other biological malfunction in a human, animal, plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

B. Principal Investigator

"Principal Investigator," in this policy, means any UNT faculty member conducting research or other educational activities utilizing UNT facilities or the person who directs a research project or program. The principal investigator (PI) usually writes and submits the grant application, oversees the scientific and technical aspects of the grant, and has responsibility for the management of the research.

C. Recombinant or Synthetic Nucleic Acid (r/s NA) Molecules

"Recombinant or Synthetic Nucleic Acid (r/s NA) Molecules," in this policy, are molecules that are constructed outside living cells by joining natural or synthetic nucleic acid segments to nucleic acid molecules that can replicate in a living cell, i.e., recombinant nucleic acids, or -Molecules that result from the replication of those described above, and -Synthetic nucleic

acid segments which are likely to yield a potentially harmful polynucleotide or polypeptide.

D. Select Agents

"Select agents," in this policy, are biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal or plant products.

IV. Policy Responsibilities

A. Generally

1. Scope of Compliance

   All UNT faculty, staff, and students shall comply with all aspects of this Policy, the UNT IBC, and the Biosafety Manual. For any research or educational use of biohazardous agents, human materials, or recombinant or synthetic DNA or RNA molecules, UNT requires compliance with Microbiological and Biomedical Laboratories (current version), the NIH Guidelines for Research Involving Recombinant DNA Molecules (current version), the OSHA and Texas Occupational Exposure to Bloodborne Pathogens Standards, the UNT Biosafety Manual (current version), the Institutional Biosafety Committee (IBC) Charter, and any additional guidelines adopted by the UNT IBC. All possession, use for research, clinical or educational purposes, and transportation of biological materials, organisms and select agents hazardous to human, animal, and plant health or environment must conform to regulations and guidelines established by federal, state, and local agencies and UNT policies.

2. Training and Procedures

   The Biosafety Officer and IBC will establish training requirements for all faculty, staff and students involved in the use of biological materials. The IBC will also establish procedures for the registration and review of biological materials and the use of recombinant or synthetic nucleic acid molecules. Researchers who plan to use or distribute biological materials including recombinant or synthetic nucleic acid molecules, biohazardous agents, animals, plants or human-sourced materials, toxins or Select Agents are responsible for knowledge of and compliance with this policy, IBC procedures and the UNT Biosafety Manual. The UNT Biosafety Manual sets forth practices and procedures to ensure that the University operates its facilities in compliance with all applicable biosafety regulations.

3. Principle Investigator Responsibilities

   Principal Investigators shall assume primary responsibility for the purchase, appropriate use, handling and disposal of all biological materials including biohazardous agents, potentially hazardous human materials, and r/s NA molecules in research or other educational activities conducted utilizing UNT facilities or due to their status as a UNT employee or student. The responsibilities of the Principal Investigator

are outlined in the current UNT Biosafety Manual and are reviewed annually and updated as required.

4. Review and Monitoring Authorization

   To protect students, faculty, staff, the community, and the environment, the UNT IBC, the Biosafety Officer and UNT RMS are authorized to review and monitor all research and other educational activities involving biohazardous agents, potentially hazardous human materials, and r/s DNA or RNA molecules, nanotechnology whether such research is funded or not.

5. Consequences of Noncompliance

   Failure to comply with this policy and the associated manuals and guidelines will result in a review by the IBC and possible suspension or revocation of approval by the IBC to work with biological material, biohazardous agents, potentially hazardous human materials, and r/s NA molecules or nanotechnology and may result in disciplinary action under the procedures applicable to faculty, staff, and students.

B. Institutional Biosafety Committee (IBC)

The UNT Institutional Biosafety Committee is responsible for the oversight of all research, clinical and teaching activities involving potentially hazardous biological materials, r/s NA molecules, and select agents. IBC responsibilities and membership are outlined in the IBC Charter and are reviewed and updated annually.

C. Biosafety Officer

The Biosafety Officer shall be appointed by the UNT Institutional Official, the Vice President for Research and Innovation. Responsibilities of the Biosafety Officer are outlined in the current IBC Charter and Biosafety Manual and are reviewed annually and updated as required.

D. Biosafety Protocol (BSP) Registrations and Approvals

Guidelines on the submission requirements for biosafety protocols and approvals are outlined in the current IBC Charter and detailed in the UNT Biosafety Manual.

E. Risk Management Services

UNT Risk Management Services is responsible for developing and administering the university's comprehensive risk management program. The risk management program as it relates to biosafety shall include, at a minimum:

1. laboratory safety and training;
2. hazardous waste collection, storage, and disposal;
3. Support Biosafety Officer and IBC for emergency planning, preparedness and response,

including business continuity and responding to health crisis;

4. environmental protection; and

5. perform routine laboratory inspections and advise and assist to identify risks, evaluate conditions that could result in personal injury, property damage, or other risks to university assets and resources, and recommend measures to avoid, prevent, reduce, or control the risk of injury or damage; or to transfer the risk of financial loss.

F. Use of Animals, Human Subjects or Radiation

In addition to IBC registration and 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:

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

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

3. Radiation – Radiation Safety Committee (RSC).

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

G. 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 biological material, biohazardous agents, potentially hazardous human materials, or recombinant/synthetic DNA or RNA 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.

H. Procedure for Reporting Violations

Any suspected violation of this policy may be reported to the UNT Biosafety Officer at the telephone number or e-mail address indicated on the Research and Innovation IBC "Contact Us" webpage or the UNT IBC at IBCprogram@unt.edu or the UNT Office of Compliance and Ethics at Compliance.UNT.edu. All such reports will be referred to the IBC for review, and if warranted, an investigation to determine if reporting to NIH along with suspension or corrective action is required.

V. Resources/Forms/Tools

Forms and instructions to be used by UNT faculty, staff, and students when submitting proposals to the UNT IBC are available at: UNT Institutional Biosafety Committee web page.

VI. References and Cross-References

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
OSHA Bloodborne Pathogens Standard
Biosafety in Microbiological and Biomedical Laboratories (BMBL)
Select Agent and Toxin List
Texas Department of Insurance Bloodborne Pathogens Standard
UNT Biosafety Manual
UNT Institutional Biosafety Committee Charter
UNT Institutional Biosafety Committee Training

VII. Revision History

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