DRAFT

Chapter 9
General Provisions
9.32 Research Administration

9.32.7 – Biosafety

I. PURPOSE

UTSA promotes the ethical and responsible use of all biohazardous agents in research. The university complies with all requirements set down in the US Federal Guidelines for Research Involving Recombinant DNA Molecules. The purpose of the *NIH Guidelines* is to specify practices for constructing and handling: (i) recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules. The University has established an Institutional Biosafety Committee (IBC) to oversee the University's compliance with those Guidelines. In addition to the activities governed by those Guidelines, UTSA has charged its IBC with overseeing the use of all infectious agents and tissue isolated from vertebrates at this University. The UTSA IBC is registered with the Office of Biotechnology Activities at the National Institutes of Health (OBA/NIH). The IBC is composed of UTSA faculty researchers experienced in the use of the biohazardous agents involved in this area, representatives from the UTSA Office of Environmental Health, Safety and Risk Management (EHSRM) and community members from outside the University, who also possess scientific expertise in relevant areas.

II. POLICY

All biohazardous agents used in research, teaching and testing at UTSA will be properly handled and contained in the safest, most responsible and most effective manner at all times by all UTSA employees engaged in funded or unfunded research involving biohazardous agents at the university.

All employees that will have direct contact with biohazardous agents at UTSA will abide by all Federal, State and University regulations that pertain to the proper handling and containment of said biohazardous agents.

III. RESPONSIBILITIES

The Senior Associate Vice President for Research Administration (SAVPRA) has been designated by the President as the Institutional Official (IO), and as such is responsible for 1) appointing the members to the IBC, and 2) ensuring that UTSA complies with all applicable laws, regulations, and policies governing the use of biohazardous agents. The IO signs forms, reports, and letters on behalf of UTSA and interacts with the Institutional Biosafety Committee (IBC) in overseeing the biohazardous agent program at UTSA.

A. The UTSA Institutional Biosafety Committee reviews research protocols for approval for performance at UTSA that involve infectious agents, recombinant DNA and the use of tissue isolated from vertebrates. In making this determination, the IBC shall assure that the research project will be conducted in accordance with the Guidelines for Research Involving Recombinant DNA Molecules insofar as it applies to the research project. This entails examination of a number of matters, including:

- **Containment levels**; some useful resources to refer to when assessing containment levels are:

  Appendices of the *NIH Guidelines*:

  - Appendix B - Table 1: Basis for the Classification of Biohazardous Agents by Risk Group (RG)
  - Appendix G – Physical Containment
  - Appendix I – Biological Containment
  - Appendix K – Physical Containment for Large Scale Uses of Organisms Containing Recombinant DNA Molecules
  - Appendix P – Physical and Biological Containment for Recombinant DNA Research Involving Plants
  - Appendix Q – Physical and Biological Containment for Recombinant DNA Research Involving Animals

  CDC and NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

  American Biological Safety Association's Risk Group Classification for Infectious Agents.

- **Facilities**;
- **Institutional procedures and practices**; and
- **Training and expertise of personnel**

B. For human gene transfer experiments, the IBC also is responsible for ensuring that:

- All aspects of Appendix M of the *NIH Guidelines* have been addressed by the principal investigator;
- Final IBC approval is granted after the RAC review process is complete; and
- Research projects are in compliance with the institution's health surveillance requirements and data and adverse event reporting requirements.

C. The IBC will also:

- Notify the principal investigator of the results of IBC review and approval.
- Set containment levels and modify containment levels for ongoing experiments as warranted;
- Implement contingency plans for handling accidental spills and personnel contamination resulting from recombinant DNA research; and
- Report to OBA and institutional officials within 30 days any:
  - Substantial problems or violations of the *NIH Guidelines*; and
  - Significant research related accidents or illnesses.

D. The committee meets once a month as necessary. Please refer to the "Important Dates and Deadlines" page of the UTSA IBC website for specific dates of meetings and submission deadlines.

E. The IBC formulates and implements procedures to assure the University's compliance with all federal regulations for the construction, handling and disposal of recombinant

molecules, organisms, and viruses containing recombinant DNA molecules and other biologically hazardous organisms and biological toxins at the University of Texas at San Antonio. The IBC reviews and exercises approval authority of all proposals for research that involves recombinant DNA molecules and other biologically hazardous organisms and biological toxins. The committee monitors all projects that involve recombinant DNA molecules and other biologically hazardous organisms and biological toxins; and maintains the required records of the review, approval and monitoring of the use and disposal of recombinant DNA molecules and other biologically hazardous organisms and biological toxins.

F. The CDC also publishes information about the Select Agent Program (SAP) at: CDC Select Agent Program. Included in that website is a page on Maximum Toxin Amounts Excluded from Regulation.

For more definitive information on the use of biohazardous materials in research at UTSA, contact the Institutional Biosafety Committee (IBC) office at ibc@utsa.edu, call the IBC Office at 458-7733 or visit the UTSA IBC website.

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