

Texas Woman's University University Regulation and Procedure

**Regulation and Procedure Name: Research Involving Recombinant DNA
and Biohazardous Agents**

**Regulation and Procedure
Number: URP: 02.410**

Policy Owner: Academic Affairs

POLICY STATEMENT

This URP defines the official process for assuring that research and teaching using recombinant DNA and biohazardous agents be conducted in a way that protects students, faculty, staff, the community, and the environment.

The TWU Institutional Biosafety Committee has the primary authority to approve, require amendments to an approved protocol, conduct post-approval review of approved protocols, disapprove or suspend research and instruction in all project involving recombinant DNA molecules and biohazardous agents at TWU.

APPLICABILITY

This policy is applicable to TWU Faculty, Staff, and Students.

DEFINITIONS

1. "Biohazard" means potentially hazardous biological agents and byproducts, including pathogenic agents
2. "Biohazardous Agents" means 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. Biohazardous agents fall into Risk Group 2 or above as defined by the NIH Guidelines for Research Involving Recombinant DNA (See NIH Guidelines, Appendix B for list of Risk Groups).
3. "Biosafety Levels (BL)" means guidelines for laboratory practices, equipment, and containment of organisms containing rDNA for the purpose of minimizing exposure. Biosafety Level 4 provides the most stringent containment conditions, Biosafety Level 1 the least stringent.

4. "Institutional Biosafety Committee (IBC)." The TWU Institutional Biosafety Committee (IBC) is a Committee that establishes responsibility for the proper use of recombinant DNA molecules and biohazardous agents in research and other educational activities at TWU (including all facilities and campuses) in order to protect students, faculty, staff, the community, and the environment. oversees all projects involving recombinant DNA or biohazardous agents.
5. "IBC Liaison" means the designated administrative officer responsible for recording committee actions, maintaining records, assisting the IBC with dissemination of information, maintaining compliance with institutional and governmental guidelines, and preparing reports.
6. "Recombinant DNA (rDNA)" means research joining natural or synthetic DNA/RNA segments outside the cell that can then be introduced and replicated in a living cell and includes derivatives that occur upon replication.
7. "Risk Groups (RG)" means classification of biohazardous agents according to their relative pathogenicity for healthy adult humans. Risk group 1 agents are not associated with disease.
8. "NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)." Document outlining principles for the safe conduct of research employing recombinant DNA technology, detailing practices and procedures for the containment of various forms of recombinant DNA research and for the proper conduct of research involving genetically modified plants and animals. Failure to comply with the NIH Guidelines jeopardizes all NIH funding at an institution.
9. "Principal Investigator (PI)" means any TWU faculty member or staff member conducting research or other educational activities involving recombinant DNA molecules or biohazardous agents utilizing TWU facilities.
10. "Significant Event" means any event which requires emergency medical intervention or is considered a major violation of NIH guidelines.

REGULATION AND PROCEDURE

I. General Information

- A. Any research at Texas Woman’s University (“TWU”), including educational activities using recombinant DNA or biohazardous agents must be approved by the Institutional Biosafety Committee (“IBC”) prior to acquisition of the agents or initiation of the activity. Any research conducted with recombinant DNA or biohazardous agents, regardless of the source of funding or source of recombinant material, must be conducted in accordance with institutional requirements and federal guidelines. TWU adheres to NIH Guidelines and appropriate TWU safety standards, as issued. Research on recombinant DNA or biohazardous agents should also be conducted in accordance with CDC/NIH biosafety guidelines (Biosafety in Microbiological and Biomedical Laboratories), as appropriate. Experiments involving animals or plants may require compliance with additional regulations and approval by the Office of Agricultural Biotechnology, U. S. Department of Agriculture, the Texas Department of Agriculture, the NIH Office of Laboratory Animal Welfare or the TWU Institutional Animal Care and Use Committee (“IACUC”). All research should comply with institutional policies.
- B. It is essential that potentially biohazardous/recombinant DNA research be conducted in accordance with the intent, as well as specific requirements and guidelines. Because research is dynamic, it is not possible to anticipate every situation. The conscientious effort and good judgment of personnel are essential for protection of health and the environment during research. Primary responsibility for compliance with institutional and governmental requirements and for safe and proper experimentation resides with the PI.
- C. The TWU IBC is an Academic Affairs Committee reporting to the Executive Vice President for Academic Affairs and Provost (“EVPAA/Provost”) through the Vice Provost for Research and Innovation and Dean of the Graduate School. The EVPAA/Provost is the signatory official who is legally authorized to represent TWU. The EVPAA/Provost appoints IBC members. The IBC members and chair review and approve research with recombinant DNA or potentially biohazardous agents on behalf of TWU. The EVPAA/Provost, President and Regents also have the authority to suspend or disapprove research, even if the IBC has approved it.
- D. The IBC is authorized to revise and update this URP and associated IBC Procedures as needed to reflect new standards, regulations, and university policies.

REVIEW

This policy will remain in effect and published until it is reviewed, updated, or archived. This policy is to be reviewed once every six years. Interim review may be required as a result of updates to federal and state law or regulations, Board of Regents policies, or internal processes or procedures.

REFERENCES

None

FORMS AND TOOLS

None

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