

Recombinant DNA and/or Infectious Biohazards in Teaching and Research

Original Implementation: January 29, 2013

Last Revision: January 31, 2017

I. Purpose

The Institutional Biosafety Committee (IBC) at Stephen F. Austin State University (SFA) is responsible for the review of proposed research activities that involve biological agents, toxins, or recombinant DNA (rDNA). This review process ensures that all university activities comply with government regulations set forth by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA), the U.S. Department of Health and Human Services (HHS), and the latest Select Agent Regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73), as applicable.

The IBC shall consist of university faculty and community representatives as set forth by the *NIH Guidelines*, and will meet monthly, or on an as-needed basis. In addition to ensuring compliance with federal agency requirements, the main goal of the IBC is to minimize risks to faculty, staff, students, facilities, the community, and the environment. All IBC procedures should be followed in conjunction with other relevant SFA policies and procedures.

II. Scope

This policy applies to all activities, teaching or research, that involve rDNA and/or biohazardous materials as defined in Section III, below, that are:

- conducted by university faculty or staff;
- conducted using property and/or facilities owned by the university; and/or
- stored at any university-owned facility

Environmental Health, Safety, and Risk Management Department (EHSRM) and IBC procedures apply to all faculty, staff, students, visitors, and agents (and their employees) that are engaged in teaching or research activities involving rDNA and/or biohazardous materials.

III. Definitions of rDNA and/or Biohazardous Materials

A. rDNA

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines) define rDNA molecules as either: (1) molecules that are constructed outside of living cells by joining of 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) above. Synthetic

DNA segments that have the potential to produce harmful or potentially harmful polynucleotides or polypeptides (e.g. toxins, and pharmacologically active agents) are considered equivalents to their natural DNA counterparts.

B. Infectious Biological Agents

Infectious biological agents include biological agents and/or biologically-derived materials that present or that may present a risk to the health and welfare of humans or animals, whether directly through infection or indirectly through damage to the environment. Categories of potentially infectious biological materials include:

- human, animal and plant pathogens (bacteria, parasites, fungi, viruses, prions);
- all human blood, blood products, tissues, and bodily fluids;
- cultured cells and potentially infectious agents these cells may contain or can support the proliferation of;
- clinical specimens; and
- infected or potentially infected animals and animal tissues

C. Select Agents and Toxins

The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), and the United States Department of Agriculture (USDA) have identified select agents and toxins that have a high potential to pose a major threat to public, animal or plant health. These agents are subject to protocol and regulatory oversight by these agencies. The HHS/CDC list of select agents and toxins (including those that overlap with USDA) are identified at 42 CFR 73.3 (HHS list) and 42 CFR 73.4 (Overlap list). The USDA list of select agents and toxins are identified at 9 CFR 121.3.

Because SFA does not have a permit of registration with the CDC or USDA, the receipt, use, or storage of select agents and toxins that are not deemed to be excluded by HHS criteria are prohibited.

IV. Risk Assessment and Selection of Appropriate Safeguards

Teaching or research activities that involve rDNA and/or biohazardous materials are classified on the basis of potential risk to humans. Risk classification determines the type of biological and physical containment level(s). There are no facilities at the university certified to conduct research or teaching above Biosafety Level 2 (BSL-2) and above Risk Group 2 (RG-2).

A. Risk Group Classification

Agents are classified into two risk groups according to their relative pathogenicity for healthy adult humans. These two risk groups are:

- Risk Group 1 (RG-1) – Agents that are not associated with disease in healthy adult humans.

- Risk Group 2 (RG-2) – Agents that are associated with human disease that is rarely serious and for which preventative or therapeutic interventions are often available.

B. Biological and Physical Containment (Biosafety Level)

The final assessment of risk, based on the agent's risk group and other risk factors, should be used to determine the appropriate biosafety level (BSL-1 or BSL-2) for the rDNA and/or biohazardous materials. The level of biosafety describes the degree of physical and biological containment required to contain rDNA and/or biohazardous materials in order to reduce or eliminate the potential for exposure of all personnel, whether inside or outside of the facility, as well as the environment.

Following is a general description of the acceptable biosafety levels at the university:

- Biosafety Level 1 (BSL-1) – Suitable for work involving biohazardous materials of a minimal potential hazard to personnel and the environment.
- Biosafety Level 2 (BSL-2) – Suitable for work involving biohazardous materials of a moderate potential hazard to personnel and the environment. The biohazardous materials are associated with human disease that is rarely serious and for which preventative or therapeutic interventions are often reliable.

Additionally, there are specific biosafety levels for work with rDNA and/or biohazardous agents involving plants or animals. Additional information on these can be found in the BMBL and the *NIH Guidelines* Section III and Appendix P (plants) and Q (animals).

V. Responsibilities

The provost and vice president for academic affairs is responsible for compliance with this policy and accompanying procedures. It is the role of the IBC to review, approve/reject, and provide oversight and guidance to individuals at the university, or that use property owned by the university, who seek to use or possess rDNA and/or biohazardous materials for teaching or research. The possession and/or use of rDNA and/or biohazardous materials at the university must be conducted with safeguards in place to protect against environmental release.

A. Laboratory Supervisors, Faculty and Staff Responsibilities

- Obtain IBC approval prior to initiating or modifying any teaching or research involving rDNA and/or biohazardous materials;
- Immediately report any significant problems or accidents and illnesses to the EHSRM, the IBC chair, and any other university committee or official that has reviewed and approved the research activity (e.g. the Institutional Animal Care and Use Committee or the Radiation Safety Officer); Comply with all local, state, and federal requirements when teaching or research involves rDNA and/or biohazardous materials;
- Comply with all local, state and federal requirements when teaching or research involves rDNA and/or biohazardous materials;

- Develop Standard Operating Procedures (SOPs) incorporating biosafety procedures or a biosafety manual prepared specifically for the teaching or research classroom or laboratory;
- Ensure that all personnel and students are properly trained on the potential hazards associated with the teaching or research activities and the necessary precautions to prevent exposures;
- Provide personal protective equipment required for work with the respective rDNA and/or biohazardous material;
- Supervise the safety performance of the teaching or research staff and personnel to ensure that the required safety practices and techniques are employed;
- Correct work errors and conditions that may result in the release of rDNA and/or biohazardous materials;
- Ensure the integrity of the biological and physical containment (biosafety level);
- Ensure the security of rDNA and/or biohazardous materials at all times; and
- Initiate or modify no rDNA research that requires prior IBC approval before initiation, until that research or the proposed modification(s) has been approved by the IBC and has met all other requirements.

B. Environmental Health, Safety, & Risk Management Responsibilities:

- Inspect periodically (minimum of one per fiscal year) all laboratories and classrooms conducting rDNA and/or biohazardous research to ensure that proper standards are strictly followed.
- Ensure that each laboratory has up-to-date standard operating procedure manuals that meet EHSRM standards.
- Report to the IBC Chair any significant problems, violations of NIH Guidelines, and any significant accidents or illnesses.
- Assist the laboratory personnel with the development of emergency plans for handling accidental spills and personnel contamination.
- Investigate accidents involving rDNA and/or biohazardous materials.
- Adopt and implement emergency plans set forth with the assistance of the safety officer for accidental spills and personnel contamination.
- Provide information on spills and incidents to public health officials as required.
- Provide advice on laboratory security.
- Provide advice to the IBC, faculty and staff on safety procedures.

C. IBC Responsibilities

- Review and consider for approval teaching or research activities involving rDNA and other potentially hazardous agents that are sponsored by, or conducted at, the university for compliance with the NIH Guidelines. This relates to initial and annual review of approval and modifications to all proposals and activities.
- Assess facilities, procedures, practices, training, and expertise of personnel taking part in such teaching or research.

- Notify the EHSRM of the IBC's review results, including approval or rejection, and the Office of Research and Sponsored Programs for externally funded research activities.
- Assess, modify and finalize containment levels for teaching or research.
- Review and report any significant problems with or violations of the NIH Guidelines, accidents, or illnesses to the provost and vice president for academic affairs and to the NIH OBA as required by section IV-B-1-j of the NIH Guidelines.

Cross Reference: *NIH Guidelines for Research Involving Recombinant DNA Molecules; Biosafety in Microbiological and Biomedical Laboratories (BMBL); 7 CFR Part 331; 9 CFR 121.3; 42 CFR 73.3-.4.*

Responsible for Implementation: Provost and Vice President for Academic Affairs

Contact for Revision: Institutional Biosafety Committee Chair

Forms: Permit Registration, Annual Renewal, Adverse Event, BSL2 SOP Template, BSL2 Manual Template

Board Committee Assignment: Academic and Student Affairs