

JACKSON STATE UNIVERSITY

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

Biosafety Policy

The Jackson State University Institutional Biosafety Committee (JSU/IBC) University oversees all research activities conducted at or sponsored by JSU, that involve recombinant DNA or synthetic nucleic acid molecules, potentially pathogenic substances/toxins, and/or human tissue/ body fluids.

Overview

The IBC follows the policies and procedures set forth in the following NIH federal guidelines and regulations. Furthermore, the IBC exercises its right to create additional safeguards as deemed necessary. The composition and duties of this committee are mandated by the federal government, as a condition of JSU receiving federal funding for research.

Federal Regulations and Guidelines

Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

The Department of Health and Human Services (DHHS) policy regulating the use of rDNA in research is entitled Guidelines for Research Involving Recombinant DNA Molecules or Synthetic Nucleic Acid Molecules. The Office of Biotechnology Activities (OBA) (within NIH) is responsible for reviewing and coordinating activities relating to the NIH guidelines.

Possession, Use and Transfer of Select Agents (42 CFR Part 73 & 42 Part 1003) and Agricultural Bioterrorism Protection Act Of 2002; Possession, Use and Transfer of Biological Agents and Toxins (7 CFR Part 331 & 9 CFR Part 121) DHHS and the United States Department of Agriculture (USDA) published rules that regulate the possession, use and transfer of a select list of biological agents and toxins.

Definitions

Recombinant or Synthetic Nucleic Acid Molecules In the context of the NIH Guidelines recombinant and synthetic nucleic acid molecules are defined as (1) recombinant nucleic acid molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell, i.e., recombinant nucleic acids; (2) nucleic acid molecules that are chemically, or by other means, synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2) above. Synthetic nucleic acid molecule segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA co

Biohazardous Materials, Agents and Toxins: Infectious biological or synthetic agents, biologically derived materials and toxins that present a risk or potential risk to the health of humans, animals, or plants either directly through exposure or infection or indirectly through damage to the environment. Categories of potentially infectious biological materials include the following:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions).
- All human and nonhuman primate blood, blood products, tissues, and certain body fluids (use of human blood and body fluid for clinical diagnostic and treatment purposes is excluded).
- Cultured cells and potentially infectious agents these cells may contain.
- Infected animals and animal tissues.

Committee Responsibilities

The IBC shall:

- 1) Establish institutional policy governing all research and teaching activities conducted by JSU personnel that involve the use of recombinant DNA or synthetic nucleic acid molecules, potentially pathogenic substances, toxins, and/or human tissue/body fluids in accordance with the applicable regulations.
- 2) Provide researchers and appropriate instructors with copies of the current guidelines, regulations and laboratory safety information, as they are made available.
- 3) Review and approve all research and instructional activities involving human tissue/body fluids, pathogenic organisms, toxins and register recombinant DNA research before the initiation of the project or course.
- 4) Inspect the laboratory facilities, in which research or laboratory courses occur involving recombinant DNA, potentially pathogenic substances/ toxins, and/or human tissue/ body fluids, to ensure that satisfactory laboratory safety measures are in use. Inspections will be based on criteria established in the appropriate federal guidelines and regulations and laboratory practices under the appropriate biosafety levels. The *Biosafety in Microbiological and Biomedical Laboratories Manual*, issued by the Centers for Disease Control and Prevention and the NIH, will also be used as a primary source of information. Additionally, the IBC in coordination with the HAZMAT office and must inspect animal care facilities when researchers are using infectious agents. In all other cases, the inspection of the animal care facilities for biosafety practices falls under the purview of the JSU Institutional Animal Care and Use Committee (IACUC).
- 5) Take disciplinary action when a laboratory facility or researcher is found to be in noncompliance with the federal guidelines and regulations. Such actions may include but are not limited to the following:
 - a) Informing the principal investigator and the Department Chair of the noncompliance;
 - b) Re-inspection to substantiate the facility is subsequently in compliance;
 - c) Referring issues of noncompliance to the Vice President for Research, for further action;
 - d) Possibly contacting the appropriate federal oversight agency, if significant noncompliance continues to occur.
- 6) Be familiar with the federal guidelines and regulations, IBC policies, and proper laboratory safety methods to ensure that they are properly executing their responsibilities.

The HAZMAT Office, which oversees and monitors the use of hazardous agents, is housed in the JSU Science and Technology building. Most, if not all laboratories are also located within the S & T building. The HAZMAT Office identifies and conducts preliminary review of all research that falls under the jurisdiction of the IBC.

Committee Membership

The Institutional Biosafety Committee is appointed by, and reports to the Vice President for Research.

- The IBC shall be comprised of no fewer than five members. At least two members shall not be affiliated with the University and shall represent the interest of the surrounding community with respect to health and protection of the environment.
- The IBC shall include members who are capable of assessing the safety of the activity and any potential risk to the public health or the environment.
- The Vice President of the Office of Research shall serve as an ex officio member of the IBC.

Principal Investigator's Responsibilities

Principal Investigators are required to:

- 1) Comply with the IBC Guidelines and appropriate federal guidelines or regulations and all conditions stated in the protocol approved by the IBC.
- 2) Submit protocol applications for all activities or modifications of activities involving recombinant DNA or synthetic nucleic acid molecules, potentially pathogenic substances, toxins, and/or human tissue/body fluids and obtain approval of the IBC prior to initiation of the activities or modifications. The investigator must submit a protocol for all recombinant DNA or synthetic nucleic acid molecules research, including the necessary Biosafety Level information, even if the experiments are exempt from the *NIH Guidelines*, for ratification by the IBC.

Ongoing projects must be reviewed at least periodically. If there is a significant change in the experiment, a new and complete form must be submitted; minor changes can be granted expedited approval by the IBC Chair, subject to review by the IBC members at the next meeting. To obtain an extension of approval of a previously approved project with no changes (except personnel) to the protocol, the researcher should submit a completed "Protocol Continuation Form" to the IBC. Approval must be obtained in writing from the IBC Chair before the researcher may continue the project past three years from the date of the original approval. Protocols are to be submitted to the Office of Research Compliance or HAZMAT Office.

- 3) Ensure that all laboratory personnel, including students, are trained in accepted procedures in laboratory safety procedures, accident techniques, and precautionary medical practices.
- 4) Adhere to the HAZMAT Laboratory Safety Plan which includes an emergency action plan for accidents and spills.

Protocol Review

1. Protocols are reviewed internally by the HAZMAT and IBC staff. At this point, one of several things will happen:
 - If the protocol does not need full committee review and contains all of the necessary information, it will be approved.

- If the protocol does need full committee review, it will be placed on the agenda for the next meeting of the IBC). IBC staff (Compliance Officer) will request any additional information needed to assist the IBC in reviewing the protocol.
2. Protocols will require full IBC review if:
 - It involves recombinant DNA or synthetic nucleic acid molecules
 - It involves Biosafety Level 3 or higher pathogens
 3. If your protocol is reviewed by the IBC, it could be:
 - Approved as written.
 - Approved with contingencies.
 - Tabled pending receipt of additional information. In this case, the protocol will need to be reviewed again at the next IBC meeting.
 4. If the protocol was approved with contingencies, one will need to submit an amended protocol addressing the contingencies. The protocol will not need to be reviewed again by the IBC; staff can verify the contingencies and approve the protocol.