

INSTITUTIONAL BIOHAZARD COMMITTEE

PRACTICES AND PROCEDURES FOR XAVIER UNIVERSITY

Revised in August 2015

**Prepared by: The Office of Sponsored Programs and
The Institutional Biohazard Committee**

EMERGENCY TELEPHONE NUMBERS

In case of an accident call:

| | |
|--|----------------------|
| Xavier University Police | 520-7490 |
| Raymond Brown | 520-5257 |
| Environmental Health and Safety Officer | 382-0165 cell |
| Dr. Shubha Ireland | 520-7585 |
| Chairman, Biohazard Committee | |

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Forward

Xavier University is committed to the safe and ethical use of biologically hazardous materials. The Institutional Biohazard Committee shall assure that all activities involving recombinant DNA, infectious biological agents and biological toxins meet the ethical and legal requirements for the responsible use of these agents. The Institutional Biohazard Committee (IBC) is responsible for reviewing all research and teaching activities conducted by faculty, staff, students and/or visiting scientists on Xavier University of Louisiana's property that involve the use of biohazardous materials: regulated animal and plant pathogens, biological toxins, Chemical toxins, and recombinant DNA molecules. The purpose of these reviews is to ensure that all activities involving biohazardous materials, and the associated facilities, are in compliance with all external regulations and applicable Xavier policies. Foremost, the IBC's objective is the protection of personnel, the general public and the environment. To this end, the IBC shall assist principal investigators and protocol directors in meeting their responsibilities; impose requirements and review policies, procedures, programs and facilities pursuant to the safe use of biological agents and other materials and toxins.

Organization and Responsibility

President of Xavier University

Associate Vice President for Research and Sponsored Programs

Institutional Biohazard Committee

Institutional Biohazard Safety Officer

Environmental Health and Safety Officer

Authorized User

While the ultimate responsibility for biohazard safety rests with the Administrative Officers of the University, the IBC shall function to discharge the University's obligations and responsibilities mandated in the NIH Guidelines (NIH), the Centers for Disease Control and Prevention Guidelines (CDC), Occupational Health & Safety Administration Regulations (OSHA) and any other requirements that overlap with our established committees at Xavier, namely Radiation Safety, Human Subjects, and Animal Care. The IBC is expected to advise Xavier and establish policies to guide principal investigators in carrying out the University's Biohazard Program in the acquisition, use, training, transfer, storage, disposal, and emergency response procedures for all biohazard materials and activities.

Committee Membership

The members of the Biohazard Committee are appointed jointly by the Sr. Vice President of Academic Affairs and the Associate Vice President for Research and Sponsored Programs. In accordance with

NIH Guidelines, the committee must be comprised of no fewer than five (5) members with experience and expertise in dealing with biologically hazardous agents including recombinant DNA technology and the capability to assess the safety of such research. The committee must consist of at least:

- A chair who has expertise in research involving biologically hazardous agents including recombinant DNA molecules, organisms and/or viruses containing recombinant DNA molecules;
- Two members not affiliated with the institution that represent the interests of the surrounding community;
- One Xavier faculty member with expertise in plant, plant pathogen, or plant pest containment principles;
- One Xavier faculty member with expertise in chemical toxins;
- The University Environmental Health and Safety Officer; and
- A biological safety officer in the event of a protocol using recombinant or synthetic nucleic acid at large scale or high containment.

Conflicts of Interest

No members of an IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

Frequency of Meetings

The Committee shall meet at least once each semester and more frequently as needed at a time and place within the discretion of the chairman. However, the full Committee must meet to review any research protocols using BI-3 agents. Review of protocols using BL-1 and BL-2 agents may be conducted by the Committee Chairperson and the University Environmental Health and Safety Officer.

Quorum and Voting

A quorum shall consist of the chair, the Environmental Health and Safety Officer and two other committee members. Minutes of the proceedings shall be recorded and circulated by the Office of Sponsored Programs to personnel having a specific interest in the proceedings. The meetings shall be conducted according to the principles of Robert's Rules of Order and the

Chairman shall use them as a guide at the request of any individual member. The order of business shall proceed as follows:

- Review of minutes of the previous meeting
- Old Business
- New Business

Responsibilities of the Committee

The Xavier's IBC is responsible for providing a safe working environment for all University activities and for compliance with all applicable federal, state, and local regulations concerning the use of biological agents, biological toxins, and recombinant DNA.

A. Chairperson of the IBC is responsible for:

1. Ensuring that the IBC is properly constituted and fulfills its requirements under the appropriate regulations, rules, etc.
2. Ensuring that all members of the IBC are adequately trained in appropriate containment practices, secondary containment procedures, and accidental spill containment procedures **in order** to fulfill their responsibilities as members of the IBC.

B. The Institutional Biohazard Committee, in general, is responsible for:

1. Advising University Official on all matters related to biohazards within their respective areas of responsibility.
2. Developing, recommending, and implementing policies and procedures for biological risk assessment and biological risk reduction throughout the University.
3. Developing emergency plans for the containment and resolution of accidental spills and other related emergencies with an emphasis on risk reduction, personnel protection, and environmental protection.
4. Monitoring all research and teaching activities involving biohazardous agents, including review and approval prior to initiation, annual reviews and updates, reviews of laboratory and safety equipment and procedures, and certifications of compliance with all applicable rules and regulations governing the use of biohazardous materials.
5. Assuring that all principal investigators are sufficiently trained in appropriate containment practices, secondary containment procedures, and accidental spill containment, as well as their responsibilities as principal investigators.
6. Advising and providing technical expertise, whenever possible, to the Institutional Health and Safety Officer on matters regarding biohazards.

7. Conducting investigations of serious violations or problems, and making recommendations to the Institutional Official for the resolution of non-compliance or serious infractions.

C. IBC Operational Guidelines:

1. IBC will review all activities involving the use of biohazardous materials prior to the start of the activities, depending on the classification of the containment level.
2. IBC will approve research protocols with or without modifications, or withhold approval of all or any portion of a protocol.
3. IBC will approve protocols for no more than five years after review at a convened meeting of a quorum of the IBC with the affirmative vote of a majority of those present.
4. IBC will review all protocol changes on an annual basis.
5. All protocols will be available for review by any member of the IBC.
6. All protocols that involve human subjects, animal testing, or radiation shall be reviewed by the IBC in coordination with the IRB, IACUC and the RSC with their respective approval numbers.
7. IBC will assess suspected or alleged violations of protocols, regulations or Xavier policies that involve biohazardous materials.
8. IBC will report all violations immediately to the Institutional Official, and request the suspension of all related activities until the IBC, the Health and Environmental Safety Officer, the Biohazard Safety Officer and the Institutional Official can review them.

D. Staff Support

The Office of Sponsored Programs (OSP) provides the necessary liaison between Principal Investigators, the IBC, granting agencies and regulatory agencies. It provides the necessary staffing and administrative assistance for the IBC.

Responsibilities of the Principal Investigator

The Principal Investigator (PI) shall:

- Ensure compliance with NIH guidelines and all conditions stated in the protocol approved by the IBC;
- Ensure that all laboratory staff, including students, are trained in the accepted procedures for: laboratory practices, containment methods, disinfection and disposal practices, utilization of all laboratory protective equipment and required actions in the event of accidental spill;
- Submit the initial research protocol and subsequent changes to the IBC for review and approval prior to the commencement of any activities;

- Develop a laboratory safety plan, including an emergency action plan for accidents and spills, as an addendum to this manual, when required;
- Ensure compliance with shipping requirements for biological agents and toxins;
- Ensure proper handling of waste disposal;
- Maintain records of microorganisms and toxins used in the laboratory and biohazard cabinets;
- Request immunizations for all personnel when necessary for their protection; and
- Maintain biohazard safety equipment in appropriate operating condition and decontaminate prior to storage or disposal.

General IBC Approval Process

I. General IBC Approval Procedures:

- A.** All Investigators intending to perform any activities involving rDNA, infectious biologicals, or biological toxins must submit a protocol to the IBC for consideration; including those activities which the PI may feel are exempt based on the NIH Guidelines.
- B.** The PI must estimate the biohazard level for the purposes of his/her application based on The NIH or CDC Guidelines.
- C.** The Institutional Environmental Health and Safety Officer and the Committee Chairperson review the protocol and forwards to the full committee for complete review.
- D.** The Protocol will be: approved, approved subject to restrictions, or disapproved in writing and recorded in the minutes.
- E.** A protocol review and approval may be deferred pending the receipt of additional information or clarification.
- F.** For recombinant DNA research plans, multiple DNA segments can be incorporated into the same petition if they share a similar source or host.
- G.** IBC approval identification numbers will be given to all protocols, including those that are exempt.
- H.** PI's may be invited to join in a committee meeting in order to answer committee members' questions, but will be excused during the voting process and discussion.
- I.** New and renewal applications that require containment at BSL-1 or BSL-2 may be reviewed by the Chairman and the Biohazard Officer.
- J.** Annual review of BL-1 and BL-2 protocols may be performed by the Chairman and the Biohazard Officer.
- K.** All BL-3 protocols, as well as any clarifications or modifications, and annual reviews of such protocols must be reviewed and approved by the full IBC.
- L.** Class 4 Biohazards are not permitted.

II. Procedures for continuing review of Protocols.

- A. Two months before the anniversary of a protocol, the PI must submit a request for review with a written summary of its progress.
- B. The Chairman and Environmental Health and Safety Officer will review the information for BSL-1 and BSL-2 protocols and issue its approval.
- C. BSL-3 protocols must be reviewed by the full committee specifically for changes in protocol and changes in regulations that require modification of the protocol, which will be handled as if it were an amendment to the protocol.

III. Five (5 Year Review Policy)

Each approved protocol shall be unique and active for a maximum period of five (5) years. At the end of this period, the approval shall automatically expire and all related activities shall be considered complete. Ongoing activities require the submittal of a new protocol and will be assigned a new IBC number. IBC numbers shall be unique and not reused.

Definitions

Biohazardous Agents

- A. Infectious/pathogenic agents classified in the following categories: Class 2, 3, and 4 bacterial, fungal, parasitic, viral, rickettsial, or chlamydial agents as defined by the NIH, or,
- B. Other agents that have the potential for causing disease or damage in healthy individuals, animals, or plants.
- C. Biological toxins include metabolites of living organisms, and materials rendered toxic by the metabolic activities of the microorganisms (living or dead).

Recombinant DNA Molecules (rDNA)

- A. Molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or
- B. DNA molecules that result from the replication of those described in "A" above.

Record Keeping

The Compliance Office, within the Office of Sponsored Programs, will serve as the Office of Record for documentation involving the IBC. Copies of all biohazard protocols shall be maintained and be made available for review by any IBC member. The minutes of **meetings**, including records of attendance and IBC deliberations shall be maintained by the OSP and shall meet Xavier's confidentiality standards. The OSP will provide the necessary documentation and forms for Principal Investigators.

Training

Committee Members and Principal Investigators must demonstrate that they are appropriately trained to use biohazards in a safe manner. This training may be demonstrated by either completing a biohazard training course or, if they have previous training, demonstrating in writing the extent of that training. Any such documentation of previous training will be evaluated by the Chairman and the Environmental Health and Safety Officer. Prior to all biohazard use, all training documentation must be on file with the Environmental Health and Safety Officer. Principal investigators are responsible for insuring that their staff will be trained regarding the appropriate Biohazard Level policies and procedures to employ with each agent and that this training is documented.

Forms

IBC Protocol Application