Lamar University
Policies and Procedures
Institutional Biosafety Committee

1. Introduction

1.0 Purpose

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It is the responsibility of Lamar University Institutional Biosafety Committee (IBC) to review, approve and oversee the use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins in teaching, research or testing activities conducted by University facilities or research personnel. Since laboratory work can involve exposure not only to recombinant or synthetic nucleic acid molecules and biohazardous agents, materials and toxins, but also to chemical and radiological hazards, the IBC Policies should be used in conjunction with any other pertinent University policies and procedures.

1.1 Mission Statement

The IBC committee provides guidance for Lamar University to safeguard human health and the environment by maintaining an adherence with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and the Biosafety in Microbiological and Biomedical Laboratories (BMBL), and the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (IODURC). The committee also assures that activities meet the ethical and legal requirements for the responsible use of recombinant or synthetic nucleic acid molecules, biohazardous agents, materials, and toxins by establishing policies and make recommendations to the University regarding such activities.

1.2 Charge and Authority of the IBC

The Associate Provost of Research and Sponsored Programs has charged the IBC with review, approval and oversight of research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins in research and teaching activities. Responsibilities of the IBC include assessment of facilities, procedures, practices, and training of research personnel to assure compliance with NIH and other pertinent guidelines and regulations. To successfully carry out these responsibilities, the IBC is appointed to achieve sufficient knowledge and expertise in biomedical research and biosafety. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure adherence to the appropriate regulations and guidelines.

The IBC makes certain that research conducted at the University is in compliance with the NIH Guidelines, BMBL, and the HHS and USDA regulations, and the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, drafts campus policies and procedures, and reviews individual research proposals using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins. The IBC is therefore responsible for establishing and implementing policies that provide for the safe conduct of research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins to ensure adherence with NIH Guidelines.

1.3 Committee Composition

The Associate Provost of Research and Sponsored Programs has the authority to appoint IBC members and alternates as needed. Members consist of faculty, research personnel, and the community. The term of membership is one year and is renewable upon mutual agreement.

Members will collectively have appropriate expertise and experience in the use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, or toxins. They must have expertise in assessment of risk to environment and public health along with knowledge of institutional commitments and policies, applicable law, professional standards, community, and environment. The IBC will have no fewer than five members who will be composed of the following:

At least one member with expertise in recombinant or synthetic nucleic acid molecules technology.

At least one member with expertise in biological safety and physical containment.

At least one member with expertise in select agents and toxins (use, storage, transfer, and disposal).

At least one member with expertise in animal containment principles.

At least one member from Environmental Health and Safety

At least one member from the surrounding community, and not affiliated with the University, to represent the interests of the community regarding health and protection of the environment.

1.4 Scope

The IBC policies apply to all research personnel engaged in activities and/or research involving recombinant or synthetic nucleic acid molecules, biohazardous agents, materials and toxins that are sponsored by the University, conducted by University

- 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.

- Ensure adherence with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines for recombinant or synthetic nucleic acid molecules research and the select agents and toxins regulations.
- Required to submit member rosters (completed b
  NIH/OBA.
- Obtain specific review, registration and/or approval from NIH/OBA for research that fall under Sections
  III-

Section 4: Meeting Process

4.0 Requirements for Quorum

The conduct of official IBC business occurs at convened meetings that must include a quorum of members for the more than half the regular voting members. A protocol is approved only if a quorum is present, and if more that 50% of the quorum votes in favor or protocol approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required. Members are expected to attend the convened meetings unless they have notified the IBC Program Coordinator in advance, that they are unable to do so. Members who fail to attend meetings on a regular basis may be removed from the committee.

4.1 Procedures

IBC meetings are routinely held every six months, or as needed. Rescheduling may occur due to inability to achieve a quorum of members and non-scheduled meetings may be called by the IBC Chair to discuss matters that arise and require immediate resolution. The IBC Program Coordinator is responsible for assuring that a meeting room is located and scheduled and that all other arrangements for the meeting are made.

4.2 Possible Review Outcomes

All non-exempt protocols are presented and discussed individually and the IBC votes on the disposition of the protocol. Possible outcomes include:

Approval When the IBC has determined that all review criteria, based on the IBC Policies and federal-mandated regulations have been adequately addressed by the Principal Investigator, the IBC may approve the research, thus providing the Principal Investigator permission to perform the research.

Approval with conditions This status is used for protocols for which all required information has not been received, required training has not been completed and/or there are remaining issues or questions regarding the safety of the3(co)-7(n)-5(v)-5(eW*n(t)13(h)-B3cl(ain)-6(in)-4(g)-5()-3(ted)-6I)-i5(eW*n5(ety)c/.62 0 612 792 reW*2 rereW*ETQ912

matters described in Section II and Section III of the NIH Guidelines (see Section 4.2). The inclusion of this material in the meeting minutes will document the biosafety aspects of each protocol.

4.5 Principal Investigator Notification

Upon completion of the review process (Section 3), the Principal Investigator will receive written notification of the