

Lamar University
Policies and Procedures
Institutional Biosafety Committee
(IBC)

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Section 1: Introduction

1.0 Purpose

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 research personnel using the University's properties and facilities.

1.5 Federal Registrations

Should a Principal Investigator request use, possession or transfer of a biological material listed as a Select Agent and/or Select Agent Toxin, and not listed as an exempt strain or quantity, the University will initiate a Laboratory Registration for Select Agents and Toxins with the National Select Agent Registry. Laboratory registrations for Select Agents and Toxins will be maintained by the Office of Research and Sponsored Programs and in the Office of Environmental Health and Safety (EHS).

1.6 Regulations and Guidelines

The IBC Policies follow the recommendations of regulations and guidelines:

NIH Guidelines specifies practices and provides guidelines for constructing and handling recombinant or synthetic nucleic acid molecules and organisms containing recombinant or synthetic nucleic acid molecules. Institutions conducting or sponsoring recombinant or synthetic nucleic acid molecules research covered by NIH Guidelines are responsible, through established policies and its IBC, for ensuring that such research is conducted in compliance with the NIH Guidelines.

BMBL is published by Centers for Disease Control and Prevention (CDC) and the NIH. This document contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is considered the standard for biosafety.

Select Agents and Select Agent Toxins. The Department of Health and Human Services (HHS), Center for Disease Control and Prevention (CDC) regulations, 42 CFR Part 73, and the United States Department of Agriculture (USDA) regulations, 9 CFR Part 121, establish requirements regarding the possession, use, receipt, and transfer of listed select agents and select agent toxins. The regulations set forth the requirements for registration of listed select agents and select agent toxins, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications. For more information visit <http://www.selectagents.gov/>.

For Research Involving Animals and Plants. The Animal and Plant Health Inspection Service (APHIS) regulates genetically engineered (GE) organisms and certain GE organisms that may pose a risk to plant or animal health. APHIS uses the term biotechnology to mean the use of recombinant or synthetic nucleic acid molecules technology, or genetic engineering to modify living organisms. Permits are required for the importation, transit, domestic movement, and environmental release of organisms that impact plants.

1.7 Definitions

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:

- 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.

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.

Dual Use Research of Concern (DURC). DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Section 2: Responsibilities

2.0 Responsibilities

The NIH Guidelines are subject to updates upon availability of new scientific data involving recombinant or synthetic nucleic acid molecules. Therefore, it is the responsibility of the University and those associated with it to adhere to the intent of the NIH Guidelines as well as the growing knowledge.

2.1 IBC Responsibilities

The responsibilities of the IBC include to review, approve and oversee research utilizing recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins research, conducted at or sponsored by the University, for adherence with the NIH Guidelines and the BMBL. This pertains to the initial and continuing reviews and modifications to the currently approved research. The IBC will notify the Principal Investigator of the results of the IBC's review, approval, or disapproval. The committee will also determine physical and biological containment for recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins research and modify containment levels, as necessary.

Assessments of the facilities, procedures, practices, training, and expertise of personnel involved in research utilizing recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents, and toxins will be performed. Suspension or the termination of protocol approvals can be required for the possession or use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins, where the IBC finds noncompliance or that such use or possession poses undue risk to research personnel or a threat to the health and safety of the community.

The IBC will periodically review the IBC policies and procedures and modify them as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements.

Protocols that include the possession and/or use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins will be reviewed for compliance with NIH Guidelines, the BMBL, and Select Agents and Toxins regulations. As part of the review process, the IBC will perform the following:

- Conduct an independent assessment of the containment levels (BSL-1 to BSL-3), as required by the NIH Guidelines or the BMBL.

- 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 by RSC) including members' biographical sketches to NIH/OBA.
- Obtain specific review, registration and/or approval from NIH/OBA for research that fall under Sections III-A, III-B, III-C and Appendix M.

2.2 Principal Investigator Responsibilities

On behalf of the University, the Principal Investigator is responsible to follow the NIH Guidelines, the BMBL and IBC Policies when using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins. Along with this understanding, the Principal Investigator has the following responsibilities:

- Make the initial risk assessment and determination of required levels of physical and biological containment in accordance with the NIH Guidelines and the BMBL.
- Be adequately trained in good microbiological techniques and provide laboratory research personnel with protocols describing potential biohazards and necessary precautions.
- Instruct, train, and supervise research personnel in (1) practices and techniques required to ensure safety, and (2) procedures for dealing with spills or potential exposures to the agents described in the research.
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics) and correct procedures or conditions that might result in release of or exposure to recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents or toxins.
- Ensure all research personnel, including students, have the required training in the accepted procedures for laboratory practices and safety.
- Obtain IBC approval prior to initiating or modifying any research involving use of recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents, and toxins. Although federal regulations allow exemptions for some types of recombinant or synthetic nucleic acid molecules use, the Principal Investigator must submit an application for all projects using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins so the IBC can verify that they are exempt.
- Maintain IBC approval for use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins through timely submission of annual updates.
- Immediately report any significant problems or any research-related accidents and/or illnesses to EHS and any other university committees.
- Comply with permit and shipping requirements for biohazardous materials.

2.3 Office of Research and Sponsored Projects Responsibilities

The Office of Research and Sponsored Programs Administration, with the help of Environmental Health and Safety (EHS), will coordinate Institutional Biosafety Committee (IBC) reviews and meetings. This is accomplished by serving as the necessary liaison between the research personnel, the IBC, federal and regulatory agencies. The Office of Research and Sponsored Programs will serve as the office of record for the IBC, and provide all necessary documentation, forms, regulatory guidelines and regulations, to Principal Investigators. If registration is necessary for the IBC committee, all forms and records will be maintained and stored via ORSPA. Communicating with the Institutional Review Board or Institutional Animal Care and Use Committee when protocols involve human subjects or animals will also be performed when necessary, overlap is visible. The ORSPA will assist in the review of allegations of non-compliance, assist in the preparation of reports, draft revised policies and procedures, and provide administrative support to the IBC.

Section 3: Protocol/Modification Submission and Review

3.0 Submissions

The IBC is responsible for overseeing and evaluating all aspects of research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins, and is charged with reviewing proposals that involve recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins to ensure that the criteria established in the IBC Policy and the federal regulations and guidelines are implemented. The primary goal of the IBC is to facilitate research personnel compliance with applicable laws, regulations, guidelines, and policies consistent with the performance of appropriate and productive scientific endeavors.

IBC protocol submissions, whether they are new IBC protocol submissions, modifications, or renewals, must be submitted to RSC by the Principal Investigator for review and IBC approval. No research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins can be initiated until the Principal Investigator has received the approval of the IBC.

Although federal regulations allow exemptions for some types of recombinant or synthetic nucleic acid molecules used, the Principal Investigator must submit an application for all projects using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins so that the IBC is aware of the activities and can verify that they are exempt.

No one shall obtain or use recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents and toxins until the protocol has been approved by the IBC. Modifications to approved protocols shall not be implemented until approved by the IBC.

3.1 Experiments Requiring IBC Review

Experiments that required IBC review include, but are not limited to:

- Studies using recombinant or synthetic nucleic acid molecules that are exempt from the NIH Guidelines.
- The deliberate transfer of a drug resistance trait to micro-organisms not known to acquire the trait naturally.
- The deliberate transfer of recombinant or synthetic nucleic acid molecules or DNA or RNA derived from recombinant or synthetic nucleic acid molecules into human research participants (human gene transfer).
- The deliberate formation of recombinant or synthetic nucleic acid molecules containing genes or sequences for the biosynthesis of toxin molecules.
- The use of RG-2 or RG-3 agents as host-vector systems.
- The use of human etiologic and animal viral etiologic agents.
- The cloning of DNA from RG-2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.
- The use of infectious or defective RG-2 or greater agents.
- Whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules or DNA derived into the germline (transgenic animal).
- Viable micro-organisms or cell lines with modified recombinant or synthetic nucleic acid molecules - tested on whole animals.
- Genetically engineered plants by recombinant or synthetic nucleic acid molecules methods.
- More than 10 liters culture of organisms or cells containing recombinant or synthetic nucleic acid molecules in a single vessel.
- The formation of recombinant or synthetic nucleic acid molecules containing one-half or more of the genome of a eukaryotic virus or from the same virus family.
- Experiments using BSL-2 or BSL-3 containment.
- Non-recombinant research using biohazardous materials, agents, or toxins.
- All research using biological toxins or bioactive derivatives or subunits of toxins.

- Research collecting or analyzing human or non-human primate cell lines, tissues, fluids, or other potentially infectious material.

3.2 New Submissions

Protocol application forms for research, teaching, and testing activities involving recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents, or toxins must be accurately completed and submitted for review and IBC approval.

To facilitate the review of protocols, Principal Investigators submitting IBC protocols will have their labs inspected and they must develop a Lab Biosafety Manual. The Biosafety Officer (BSO), as agent for the IBC, will assist the Principal Investigator in completing this step of the application. For information on this process and Biosafety Manual Templates go to EHS website.

Upon submission, the protocol will be reviewed for completeness by the Research Compliance Specialist, and Principal Investigator may need to submit additional information to ensure a complete submission, if requested.

Approval/Non-approval will be determined by the IBC, and the Principal Investigator will be notified of the decision.

3.3 Continuing Review / Renewal

The Principal Investigator is required to resubmit their legacy rDNA or Biosafety protocols for renewal or a continuing review application for annually. The Principal Investigator will be notified of pending expiration of approval at regular intervals prior to expiration of approval period. All annual renewals of legacy rDNA and Biosafety protocols and continuing review of with significant changes are reviewed in the same manner as new protocol submissions (see Section 4.1.1). Continuing reviews of protocols without changes or with non-significant changes may be reviewed by designated reviewers and approved administratively (see Section 4.1.2). Research cannot be continued if protocol renewal or continuing review is not approved prior to the expiration date of the previous approval period.

3.4 Modification Process

Changes or modifications to approved protocols (i.e., change in or additional of research personnel, room changes, new procedures, or agents) must be reviewed and approved by the IBC prior to initiation.

Major changes are those that change the scope of the review or that are inconsistent with the focus of the approved protocol. For major changes, the PI should submit a new protocol. Significant changes will be reviewed by designated review and require approval at a convened IBC meeting. Proposed significant changes require designated review and IBC approval prior to initiation. Minor-risk changes are changes to approved protocols including recombinant that that are minor, do not affect the risk assessment or applicable NIH Guidelines.

Minor-risk changes can be reviewed through designated review by designated qualified member(s) and may be approved outside a convened IBC meeting. Proposed minor-risk changes require designated review and IBC approval prior to initiation.

3.5 Protocol Termination

The Principal Investigator will notify the IBC Program Coordinator when a protocol involving recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents and toxins is completed or no longer active. The IBC shall contact the Principal Investigator if there are any questions or concerns regarding closure of a protocol.

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 meeting to be held. The IBC defines a “quorum” as more than half the regular voting members. A protocol is approved only if a quorum is present, and if more than 50% of the quorum votes in favor of 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 the protocol.

Tabled – If the protocol requires clarification for the IBC to make judgment, certain committee members with certain expertise is not present, the IBC wishes to seek external consultation, or any of a number of other reasons prevents the IBC from conducting its review, then the IBC may wish to defer or table review.

Withhold Approval- When the IBC determines that a protocol has not adequately addressed the requirements of the IBC Policies and regulations as applicable, the IBC may withhold approval. A IBC Subcommittees may not withhold approval; this action may only be taken if the review is conducted using the IBC method of review.

4.3 Conflict of Interest

Should an IBC member declare involvement in any way in a research protocol under review by the IBC, or state a conflict of interest with a research protocol, then the member(s) are excluded from discussion and voting except to provide information requested by the IBC. They may be asked to leave the meeting room for discussion and voting and are not counted toward a quorum.

4.4 Minutes

Review of protocols by the IBC invokes a deliberative process, and section IV-B-2-b of the NIH Guidelines require that the IBC meeting minutes should offer sufficient detail about the discussion of the matters that were discussed to document the IBC rationale for decisions.

To document the adequate fulfillment of the Committee’s review and oversight responsibilities described in Section IV-B-2-b of the NIH Guidelines, the meeting minutes should also document the IBC’s consideration of several

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 review decisions (approved/not approved) and whether any special conditions for approval of work is required. Included in the notification will be the IBC decision on the biocontainment/biosafety level to be used for the proposed research, any special safety considerations, applicable sections of the NIH Guidelines, along with the approval period (begin/end dates).

4.6 Reports to the Institution Official

Copies of minutes and reports of laboratory incidents, accidents, spills, potential or actual exposure to infectious or biohazardous materials, and incidents of non-compliance, protocol suspensions or terminations will be forwarded to the IO. For many of the above, the IO may be required to file a report with the Office of Biotechnology Activities or other agencies .

Section 5: Reporting Requirements

5.0 Reportable Incidents and Violations

Incidents/problems involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins must be immediately reported to the Environmental Health and Safety. Examples of reportable significant incident include but are not limited to any overt exposure, such as a needle stick, splash, and contamination due to equipment failure, and any potential exposure in a BSL-3 facility. A significant event may also occur from a containment breach, which may be subsequently determined to pose either an overt or potential exposure to individuals. It should be noted that waste from recombinant or synthetic nucleic acid molecules research is also considered biohazardous and incidents involving improper disposal of recombinant or synthetic nucleic acid molecules must also be reported.

5.1 Principal Investigator Reporting

The Principal Investigator and their personnel must report any significant incident, violation of the NIH Guidelines, or any significant, research-related accidents and illnesses immediately by contacting the IBC.

5.2 IBC Reporting

The IBC is required, by the NIH Guidelines, to report to the appropriate University official and to the NIH/OBA within 30 days any significant incidents, violations of the NIH Guidelines, or any significant research-related accidents and illnesses copies of these reports should be sent to the Research Compliance Officer. The IBC will be responsible to determine what actions, if any, are necessary.

Section 6: Training

Training

Training is required for all research personnel working with recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins. Completion of the courses is a requirement for the approval of new and continuing Biosafety and Recombinant protocols. Training can be found on www.citiprogram.org. Investigators are complete the Initial Biosafety Basic Course.

6.0 IBC Member Training

All IBC members will complete the CITI initial IBC training. The training program for all members consists of information provided at each IBC meeting. The objectives of providing ongoing training for IBC members is to

increase their knowledge, understanding and awareness of current laws and regulations, new directives, best practice guidelines and institutional policies. It also provides a regular forum for the IBC to discuss concerns or questions brought forth by the faculty and research personnel.

6.1 Principal Investigator and Research Personnel Training

General biosafety training at www.citiprogram.org is mandatory for all Principal Investigators and research personnel. The NIH Guidelines (CW512) training is mandatory only for Principal Investigators and research personnel performing recombinant or synthetic nucleic acid molecules research that is non-exempt. It is the Principal Investigator's responsibility to complete and ensure all research personnel has received the required training prior to protocol review by IBC. Documentation of successful completion of training is required to receive IBC approval.