LAMAR UNIVERSITY
MANUAL OF ADMINISTRATIVE POLICIES AND PROCEDURES

SECTION: Academic Affairs **MAPP 02.07.06**
AREA: ORSPA

Institutional Biosafety Committee

I. POLICY

A. At Lamar University, our commitment to fostering a culture of excellence in research, innovation, and academic pursuits is paramount. To ensure the integrity, quality, and effectiveness of our research endeavors, it is essential to define terms, establish responsible parties, and provide guidance.

II. PURPOSE AND SCOPE

A. 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.

B. Continuous growth of research enterprises is a critical priority as Lamar University continues its mission to seek new knowledge and contribute to the larger academic and professional community. Promoting public good by fostering the transfer of knowledge gained through research to the private sector is a vital element of this mission. The University holds its research and sponsored program activities to the highest standards of moral, ethical, and legal bases of operation.

C. 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.

III. REGULATORY BASIS

A. IBCs are primarily governed by the NIH **Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**. These extensive guidelines first began in 1994 and have been updated several times since their inception, serving as the basis of regulation for controlled materials subject to this policy.

IV. DEFINITIONS

A. **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:

1. Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions).

2. 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).

3. Cultured cells and potentially infectious agents these cells may contain.

4. Infected animals and animal tissues.

B. **Chief Research Officer.** An individual ultimately responsible for the oversight of funded research and sponsored programs at Lamar University. At Lamar University, the Chief Research Officer is the Associate Provost for Research. The Chief Research Officer may designate an appropriate official to act on their behalf.

C. **Dual Use Research of Concern (DURC).** 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.

D. **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.

3. Molecules that result from the replication of those described in (1) or (2) above.

E. **Researcher**. All Individuals who are engaged in research, whether funded or unfunded, or in sponsored programs activities. For the purposes of this policy, the term researcher refers to any Lamar University faculty or staff member having direct responsibility for the design, conduct or reporting of funded or unfunded research or other sponsored programs activities funded or proposed for funding by the federal government or other external funder.

F. **Research Compliance Officer**. An individual responsible for interpreting and enforcing compliance across all research and sponsored programs enterprises across the University. This officer shall be appointed by the Chief Research Officer and work within the Office of Research and Sponsored Programs Administration.

V. COMMITTEE CHARGE AND AUTHORITY

A. The Associate Provost for Research 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.

B. 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.

VI. COMMITTEE COMPOSITION

A. The Associate Provost for 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.

B. 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:

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

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

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

4. At least one member with expertise in animal containment principles.

5. At least one member from Environmental Health and Safety

6. 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.

C. An individual may fulfill one or more of the above roles, provided that the total committee numbers at least five members and the overlapping roles do not conflict.

VII. FEDERAL REGISTRATION

A. Should a Principal Investigator request use, possess or transfer 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 Administration (ORSPA) and in the Office of Environmental Health and Safety (EHS).

VIII. ROLES AND RESPONSIBILITIES

A. **Chief Research Officer.** The Associate Provost for Research and the Office of Research and Sponsored Programs Administration bear responsibility for all sponsored grants and contracts concerning animal care and use. The Chief Research Officer appoints members of the IBC and carries ultimate oversight of these activities.

B. **IBC Committee**. 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.

C. 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.

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

2. 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:

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

6. 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.

7. Submit member rosters (completed by RSC) including members' biographical sketches to NIH/OBA.

8. 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.

D. **Office of Research and Sponsored Programs Administration**. The Office of Research and Sponsored Programs Administration shall be represented by the Research Compliance Officer as appointed by the Chief Research Officer. This individual has the following responsibilities:

1. Maintaining current and accurate files on every researcher involved in biological research.

2. Requesting updated disclosures and approvals from researchers at the time of funding.

3. Developing approved management plans when applicable.

4. Liaising with federal regulatory agencies on behalf of the University and the IBC.

5. Providing and maintaining relevant training to researchers.

6. Investigating non-compliance or misconduct.

E. **Researchers** must successfully complete appropriate trainings, as assigned by the Research Compliance Officer, prior to carrying out any research. This is required for all undergraduates, graduate postdoctoral researchers receiving wages (or working as volunteers) or receiving academic credit for participating in research. Upon completion of the online training, certification of the course is provided. Individuals conducting research subject to this policy must:

1. Make the initial risk assessment and determination of required levels of physical and biological containment in accordance with the NIH Guidelines and the BMBL (PDF).

2. Be adequately trained in good microbiological techniques and provide laboratory research personnel with protocols describing potential biohazards and necessary precautions.

3. 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.

4. 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.

5. Ensure all research personnel, including students, have the required training in the accepted procedures for laboratory practices and safety.

6. 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.

7. Maintain IBC approval for use of recombinant or synthetic nucleic acid molecules and biohazardous materials, agents, and toxins through timely submission of annual updates.

8. Immediately report any significant problems or any research-related accidents and/or illnesses to EHS and any other university committees.

9. Comply with permit and shipping requirements for biohazardous materials.

IX. IBC SUBMISSION AND REVIEW PROCESS

A. **Research Requiring IBC Oversight**. Studies that require IBC review and approval include, but are not limited to:

1. Studies using recombinant or synthetic nucleic acid molecules that are exempt from the NIH Guidelines.

2. The deliberate transfer of a drug resistance trait to micro-organisms not known to acquire the trait naturally.

3. 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).

4. The deliberate formation of recombinant or synthetic nucleic acid molecules containing genes or sequences for the biosynthesis of toxin molecules.

5. The use of RG-2 or RG-3 agents as host-vector systems.

6. The use of human etiologic and animal viral etiologic agents.

7. The cloning of DNA from RG-2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.

8. The use of infectious or defective RG-2 or greater agents.

9. 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).

10. Viable micro-organisms or cell lines with modified recombinant or synthetic nucleic acid molecules - tested on whole animals.

11. Genetically engineered plants by recombinant or synthetic nucleic acid molecules methods.

12. More than 10 liters culture of organisms or cells containing recombinant or synthetic nucleic acid molecules in a single vessel.

13. 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.

14. Experiments using BSL-2 or BSL-3 containment.

15. Non-recombinant research using biohazardous materials, agents, or toxins.

16. All research using biological toxins or bioactive derivatives or subunits of toxins.

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

B. **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.

1. 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.

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

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

C. **Continuing Review and 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.

1. Continuing reviews of protocols without changes or with non-significant changes may be reviewed by designated reviewers and approved administratively. Research cannot be continued if protocol renewal or continuing review is not approved prior to the expiration date of the previous approval period.

D. **Modification.** 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.

1. 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.

2. 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.

E. **Reportable/Adverse Events.** 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.

1. 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.

F. **Protocol Closeout.** 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.

X. COMMITTEE MEETING

A. **Scheduling**. 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 Research Compliance Officer is responsible for assuring that a meeting room is located and scheduled and that all other arrangements for the meeting are made.

B. **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 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.

C. **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:

1. **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.

2. **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.

3. **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.

4. **Deny 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.

D. **Conflicts 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.

E. **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.

F. 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. The inclusion of this material in the meeting minutes will document the biosafety aspects of each protocol.

G. **Notification**. Upon completion of the review process, 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).

XI. NON-COMPLIANCE

A. Lamar University requires that all researchers comply fully, truthfully and in a timely manner with this policy. Instances of deliberate breach will subject the researcher to disciplinary actions under policies of Lamar University and the Texas State University System. Such action could result in a formal reprimand, non-renewal of appointment, termination of appointment, or other enforcement action.

B. If the failure of a researcher to comply with this policy has biased the design, conduct or reporting of funded or unfunded research or sponsored programs activities, Lamar University will promptly notify the appropriate granting agency, sponsor, or other appropriate agency of the incident and corrective action will be taken.

XII. EDUCATION AND TRAINING

A. The University will provide education and training sessions through the CITI system on animal care and use regulations and best practices to ensure researchers understand their obligations and responsibilities.

XIII. REVIEW AND RESPONSIBILITY

Responsible Parties: Academic Policy Advisory Council; Office of Research and Sponsored Programs Administration.

Review Schedule: Every three years on or before the date the policy was last revised and/or approved.

XIV. APPROVAL

Dr. Brett Welch	11/08/2024
Interim Provost and Vice President for Academic Affairs	Date

Dr. Jaime Taylor	11/08/2024
Lamar University President	Date

POLICY LOG

Version	Date	Description of Changes
1	01/01/2011	Issued.
	08/01/2023	Last updated.
		Reviews by constituency groups completed.
		Review by campus community completed.
		Policy approved by President.

APPENDICES

Related Links

Office of Research and Sponsored Programs Administration (https://www.lamar.edu/research/research-and-sponsored-programs.html)
NIH FAQ on IBC Administration (https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/faqs-on-institutional-biosafety-committee-ibc-administration-april-2024/)
NIH Guidelines (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm)

Hard copies of this document are considered uncontrolled and potentially inaccurate by the Office of Research and Sponsored Programs Administration. Please refer to the Office of Research and Sponsored Programs Administration website for the official, most recent version.