Alabama College of Osteopathic Medicine

Biosafety Policy

PURPOSE

Biological safety is the discipline that addresses the safe handling and containment of biohazardous materials in order to protect humans, animals, plants and the environment. The Biosafety policy describes the College's stance on the regulation, handling, containment and disposal of biohazardous material.

The existence of an Institutional Biosafety Committee (IBC) is required by the National Institutes of Health (NJH) for research involving recombinant and synthetic nucleic acid molecules. The Alabama College of Osteopathic Medicine (ACOM) IBC reviews, approves and oversees projects in accordance with the responsibilities defined in Section IV-B-2 of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. ACOM has expanded the scope of the IBC to include oversight, administration and review of College policies and research involving any microorganism, biologic toxin, or other biologic material which may pose a threat to humans, animals, plants or the environment. The IBC is charged with providing institutional assurance to the Dean that research is conducted according to current local, state and federal guidelines and regulations relating to the use and disposal of biohazardous material. To this end, the IBC assists and advises researchers in meeting their responsibilities to ensure that all biological aspects of research are conducted in a safe manner using established biosafety standards, principles and practices.

The IBC is sanctioned to withhold authorization of any studies not explicitly approved by the Centers for Disease Control and Prevention (CDC) NIH Guidelines until containment requirements are established.

POLICY

The Alabama College of Osteopathic Medicine will follow all current federal, state and local regulations/guidelines for the handling and containment of biohazardous material. This policy applies to all faculty, students, staff, visitors and contractors at The Alabama College of Osteopathic Medicine.

DEFINITIONS

1) Biohazardous materials: Any material of biologic origin that is potentially hazardous to humans, animals, plants and the environment including but not limited to:
   a) Known pathogenic agents: bacteria, viruses, fungi, parasites and prions.
   b) Nucleic acids used in genetic manipulations (recombinant DNA technology, synthetic biology).
   c) Cell lines: human or non-human primate derived; lines deliberately infected with a pathogen or exposed to a biologic toxin; any recombinant cell line.
   d) Animals including research and wild animals that are known or suspected to harbor pathogenic organisms.
   e) Toxins of biologic origin.
   f) Plant materials including those that are known or suspected to harbor plant pathogens or plant pests; transgenic plants; and exotic plants.

g) Animal materials including transgenic animals; blood, blood components, body fluids, tissues or organs from animals known or suspected to harbor pathogenic organisms.
h) Human materials including human blood, blood components, body fluids, tissues or organs.
i) Vectors including arthropods that are known or suspected to harbor pathogenic organisms.
j) Select agents are agents that have been determined by the federal government as being capable, if released, of causing a serious public health crisis or are high consequence agricultural pathogens. The select agent lists can be found in 42 CFR Part 73 (human and overlap), 7 CFR Part 331 (plant), and 9 CFR Part 121 (animal).

2) Containment refers to the safe work practices, equipment and facility design used to reduce or eliminate exposure of laboratory workers, other persons and the outside environment to potentially hazardous materials.
3) Four biosafety levels (BSL) that describe increasing levels of containment are defined in the Centers for Disease Control's publication Biosafety in Microbiological and Biomedical Laboratories (BMBL).
4) Dual Use Research of Concern is research that can be reasonably anticipated to provide knowledge, products or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, or the environment.

FUNCTIONS AND RESPONSIBILITES OF THE IBC

Specific functions and Responsibilities are as follows:

- Review, approve and monitor all ACOM research projects involving biohazardous material for which BSL-2 or greater containment and practices are required.
- Review, approve and monitor all ACOM research projects that fall under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.
- Ensure administration of the biological safety program at ACOM.
- Review IBC procedures annually.
- Assess containment levels, facilities, procedures, practices, training and expertise of personnel involved in proposed research in accordance with current biosafety standards.
- Notify the Principal Investigator (PI) of the results of the IBC review and approval process.
- Review and approve ACOM policies in accordance with federal regulations and guidelines that cover biological safety and make recommendation s to the Vice President on relevant biosafety matters. Review and adopt ACOM emergency plans covering accidental spills and personnel contamination resulting from research using potentially hazardous biological materials. Review site safeguards and security plans for biologic materials.
- Review incidents and determine level of significance, level of violation, and assess required action. When appropriate, investigate potential violations of the NIH Guidelines or ACOM policies, research-related accidents or illnesses involving hazardous biological materials, and any incidents or problems involving hazardous biological materials that may be called to the Committee's attention. Report results of such investigations to the respective responsible Department Head, and to the Biological Safety Officer (BSO) and the Vice President. Report significant problems or violations to the NIH Office of Biotechnology Activities (OBA) as per Section IV-B-2-b-(7) of the NIH Guidelines and as per OBA FAQ guidance document on incident reporting.
- Maintain reviews, minutes and reports in an orderly and retrievable fashion.
- Submit an annual report to NIH OBA that includes a current membership roster detailing relevant roles and biographical sketches for new members and updated biographical sketches for existing members.

- Advise division heads, principal investigators and other academic and administrative officers of changes in rules and recommendations of various government agencies relating to biosafety.

Specific Functions

- The IBC Chair is responsible for the training of all IBC members.
- The Biological Safety Officer is the administrator of the IBC and is responsible for the day-to-day operations of the Biosafety Program.

Meetings

The meeting format should facilitate the taking of minutes and accommodate public attendance. Acceptable approaches for satisfying the NIH Guidelines include face-to-face meetings and the use of technology such as teleconferencing or videoconferencing. Meetings are open to the public, and minutes will be provided upon request in accordance with state and federal laws and ACOM policy.

The IBC will conduct meetings as needed for the conduct of business. A proposed agenda will be developed and distributed before each meeting. Meetings will proceed and official business be conducted only when a quorum, defined as more than half of the voting members, is present. All research subject to the NIH Guidelines must be reviewed at a convened meeting of the IBC with a quorum present. Meeting minutes will be taken to accurately reflect the topics of discussion. Minutes will be reviewed, approved by the members and maintained on file.

Confidentiality

All business of the IBC shall be subject to disclosure according to the NIH Guidelines and the Freedom of Information Act. Research reviews and other business of the IBC shall be conducted in compliance with these policies, guidelines and laws in such a matter as to preserve the academic freedom and confidentiality of the processes, participants and stakeholders to the extent possible.

Conflicts of Interest

No member of the IBC may review or vote on a project with the following conflicts: Institutional conflict of interest

- Conflicts of commitment
- Individual conflicts
- Financial
- Competing

PROCEDURE FOR APPLICANT

Biosafety is monitored by the Institutional Biosafety Committee (IBC)- a standing committee that reports to the Dean. The IBC is responsible for the review of all research projects using biohazardous materials including laboratory, animal and field studies. In addition, the IBC is responsible for formulating and recommending biosafety policies and establishing procedures for the handling of nonradioactive biohazardous waste; reviewing and advising with regard to situations that represent potential biological hazards including dual use research of concern; and reviewing research personnel, facilities, procedures and proposals involving biohazardous material. The IBC is the only entity with the authority to review all proposed research involving biohazardous materials performed under the auspices of The Alabama College of Osteopathic Medicine. The IBC is authorized to create specific procedures that relate to the operation of the program.

All research involving biohazardous material must be reviewed and approved by the IBC prior to initiation of the research. The IBC's authority is granted by the Dean who is the Institutional Official. The IBC has the authority to act independently to bind all activities falling under their purview.

Biological safety is represented by the biological safety officer (BSO) who is appointed by the Dean and is responsible for implementing College policies and procedures set forth by the IBC; monitoring compliance; reporting problems; investigating incidents; assisting laboratory directors and principal investigators in training of personnel; and providing technical advice on biosafety and biosecurity matters. The biosafety office also provides guidance in current biosafety practices to non-research related areas such as teaching and clinical laboratories.

1) IBC Oversight and Approval

   Any individual planning to (a) use microorganisms, biological toxins, or other materials which may pose a hazard to humans, animals, plants or the environment, for which biosafety level 2 or greater practices, techniques, equipment, or facilities are required or (b) employ recombinant DNA technology must not do so without prior IBC approval. The Biosafety Office should be contacted prior to proposal submission or, in the case of non-funded research, prior to study initiation. All laboratories and animal facilities certified to be biosafety level 2 or above are to be inspected by the BSO on a periodic basis. Individuals planning to obtain materials referenced above for which biosafety level 2 or greater practices, techniques, equipment, or facilities are required must contact the BSO prior to receipt of such materials.

2) Consequences of Noncompliance

   It is imperative that biosafety policies and procedures be strictly followed to ensure the safety of workers and to ensure compliance with government guidelines and regulations. Noncompliance may jeopardize the ability of the College to obtain federal funding or result in suspension of work of all federally funded research. Grantees and contractors must be prepared to demonstrate that proper standards have been put in place or practice.

REVIEW

This policy and procedure statement will be reviewed as needed by the BSO and IBC with recommendations for revision presented to the compliance office for review.