

2. PROGRAM ADMINISTRATION

The policies, rules, and procedures set forth in the UAB Safety Manuals have a single, straightforward purpose: to promote a safe environment for the protection of University of Alabama at Birmingham employees, students, visitors, our community as well as UAB property. In order for these rules and procedures to be effective, it is important to have a structured administrative format in place that defines the roles and responsibilities of each person or administrative office.

2.1 Office of the Vice President for Research

The Office of the Vice President for Research and the Office of the Vice President for Financial Affairs share responsibility for the implementation of campus safety programs at UAB. The Vice President for Research has responsibility for ensuring that research is conducted in full conformity with the provisions of the safety manuals and all federal, state, and local regulations. All University research units with responsibility for any aspect of biohazards or potentially infectious materials must coordinate their activities through the UAB Department of Occupational Health & Safety, which has a dual reporting line to the Vice President for Research Safety and the Vice President for Financial Affairs.

The University and its administrative officers are ultimately responsible for:

- Promoting the importance of safety in all activities
- Supporting a broad-based research safety program that will protect UAB laboratory personnel, visitors, students, and the community from ill-health effects and injuries associated with the use of hazardous agents in use in UAB facilities
- Assigning responsibility for the program components to appropriate individuals, task forces or committees and identifying and implementing clear lines of authority
- Providing facilities that meet University requirements for working with hazardous materials

The Executive Directors of UAB Hospital in conjunction with Director of Hospital Planning and Management and the Manager of Policies and Standards Resources are responsible for ensuring that hospital activities are conducted in conformity with Hospital Standard Policies and Procedures.

2.2 UAB Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) is one of several safety committees with membership appointed by the UAB President. The IBC is responsible for assessing risk(s) and potential environmental impacts associated with campus activities involving biological and chemical agents and making recommendations for safe conduct of such activities. It is important for faculty and staff members to understand that certain information in Committee files may be subjected to public scrutiny under a disclosure provision of current NIH guidelines. Upon request, minutes of IBC meetings pertaining to recombinant DNA/RNA activities and documents or reports submitted or received from federal funding agencies are required to be made public. These may include documents such as project registration documents, research related accidents, and facilities inspection reports.

IBC responsibilities are outlined in [Appendix A](#).

2.3 The [Department of Occupational Health & Safety](#)

The safe operations and activities of UAB are vital to its very existence. Whether the activity is teaching, conducting research or delivering health care, it must be done in a way that is as error free as possible, is top quality and is a final product that is acceptable to those receiving it and to the surrounding community.

The Department of Occupational Health and Safety is functionally organized into the following program operational units (alphabetically listed):

- Asbestos Abatement
- Biological Safety
- Chemical Safety
- Education and Training
- General Safety
- Hazardous Waste Management
- Hospital and Clinic Safety
- Information Technology
- Radiological Health and Safety

Program area reporting is through the Assistant Vice President for Occupational Health and Safety to the Associate Vice President for Facilities and the Vice President for Research. In an effort to minimize requirements and to make sure fairness is upheld, the University has established several safety committees that set UAB policies regarding the acquisition, use, handling and final disposal of potentially hazardous materials. These policies are set forth in the form of "safety manuals" and represent a summation of regulatory requirements and agreements as to how these activities will be conducted at UAB. All health and safety manuals are signed and therefore endorsed by the President and in many cases are part of the licensing application and agreement with the regulatory agency.

There are currently four major health and safety committees:

- Radioactive and Radiation Safety Committee
- Institutional Biosafety Committee
- Hospital Safety Committee
- General Safety Committee

Membership for all committees is composed of researchers and/or faculty, UAB administrators and OH&S staff. Cross-membership with other institutional committees is emphasized to reduce paperwork for PIs and provide coordinated comprehensive review and reporting of research activities (e.g. Institutional Animal Care and Use Committee, Institutional Review Board, Hospital Infection Control).

2.3.1 Biosafety Division

The Biosafety Division fosters safe Biosafety practices and compliance through implementation of policies, guidelines, or regulations set forth by University Administration, the Institutional Biosafety Committee, and regulatory and granting agencies.

The Biosafety Division, under the direction of the Director of Biosafety, is responsible for implementing and overseeing the technical aspects of the campus Biological Safety Program and includes the following services:

- Provides advice to faculty and staff on Biosafety matters.
- Reviews Project Registration including Recombinant DNA/RNA Registration, performs laboratory audits, and prepares recommendations for the IBC.
- Provides guidance on practices and procedures for laboratory use of recombinant DNA/RNA (rDNA/RNA) and infectious materials.
- Provides consultation on the purchase of biological safety cabinets (BSC), and other laboratory ventilation equipment.
- Reviews plans for new labs and renovations and provides recommendations on lab ventilation and lab design.

- Certifies biosafety cabinets, fume hoods, and clean air benches; performs other laboratory ventilation evaluations.
- Provides biological safety education and training aids and develops educational and training programs.
- Provides consultation for shipping infectious agents.
- Assists in coordinating and implementing the UAB Medical Waste Management Plan and conducts related training.
- Coordinates the Select Agent Program for biological agents.
- Provides consultation for clean-up and decontamination of biohazardous accidents or spills.
- Performs periodic audits of laboratory facilities.
- Performs environmental assessments involving hazardous biological material.
- Assists PIs and staff in performing laboratory and project specific risk assessments.
- Collaborates with other OH&S staff to further promote a University-wide safety environment.

2.3.2 The Biosafety Officer's (BSO) duties include, but are not necessarily limited to, providing technical advice to the IBC and researchers on laboratory containment and safety procedures, overseeing periodic inspections to ensure that laboratory standards are maintained, and developing guidelines for handling spills and personnel contamination. The BSO reviews and approves Biosafety Level 1 project registrations, exempt recombinant DNA/RNA projects, projects involving the use of material of human origin, and serves as a member of the Institutional Biosafety Committee.

2.4 Dean/Department Chairs/Directors

Deans, Department Chairs, and Directors are responsible for:

- Taking appropriate measures to assure that university/department/division activities comply with all relevant research safety policies, laws, regulations, and guidelines.
- Ensuring that staff have had instruction in laboratory safety and security procedures appropriate for their assignments
- Ensuring that students have had instruction in laboratory safety and security procedures in teaching laboratories or field situations where biohazardous agents are used or encountered.
- Identifying technically qualified laboratory safety coordinators for the unit and providing adequate training and time to carry out the assigned responsibilities.
- Ensuring that emergency response plans are in place for their areas and facilities of responsibility.
- Providing OH&S with the name of the designated laboratory safety coordinator for their respective units.

2.5 Principal Investigators / Laboratory Directors

The Principal Investigator (PI) / Laboratory Director (LD) is directly and primarily responsible for full compliance with the policies and procedures described in the Biosafety Manual. This responsibility extends to all aspects of Biosafety involving all individuals who enter or work in the PI's/LD's laboratory or collaborate in carrying out the PI's research. Although the PI/LD may choose to delegate aspects of the safety program in his/her laboratory to other laboratory personnel or faculty, this does not absolve the PI/LD from the ultimate responsibility.

Responsibilities include but are not limited to:

- Develop and implement written laboratory specific biosafety and security procedures (Laboratory Safety Plan) consistent with the nature of current and planned research

activities; develop emergency plans for handling hazardous spills and potential exposure events.

- Ensure that all laboratory personnel, including other faculty members, understand and comply with the Laboratory Safety Plan.
- Ensure that all laboratory personnel, maintenance personnel, and visitors who may be exposed to any biohazard are informed in advance of their potential risk and of the behavior required to minimize that risk.
- Register projects with OH&S and IBC that involve the use of recombinant DNA/RNA, microbial agents or products, human blood or body fluids, human gene transfer, human or non-human primate primary cell/tissue culture, the introduction of any of the above material into animals; register projects that require a letter of approval to the granting or funding agency; register projects that require signature of the University Safety Officer; register projects that involve the use, possession, or transfer of any quantity of agent listed on the select agent list.
- Delay initiation or modification of biohazardous materials use that requires Institutional Biosafety Committee approval (e.g., Biosafety Level 2 or greater containment required or non-exempt recombinant DNA/RNA work) until that work, or the proposed modification has been approved by the IBC and has met all other requirements of the Biosafety Manual.
- Ensure that any research project, that requires review or approval before initiation by institutional safety officials or committees in order to comply with the NIH Guidelines or any other funding agency requirements, be reviewed and approved before seeking or obtaining agency approval. Allow 4-6 weeks for IBC review.
- Assure that personnel working with biohazardous materials are aware of the hazards and proficient in the practices and techniques required for the safe handling of such materials. All training must be documented with records retained for a minimum of 3 years post employment or longer if required by laboratory specific regulatory or accrediting bodies.
- Assure that permits required by the United States Department of Agriculture (USDA) and/or the United States Public Health Service (USPHS) for work with animal or plant pathogens are obtained.
- Follow importation, exportation, and interstate shipping requirements for biological material. Obtain permits as indicated.
- Immediately report to the BSO all significant violations of the policies and procedures and all significant research-related accidents (spills, needle-sticks, exposures, injuries, etc.) that result in overt or potential exposure to infectious materials. (See the UAB On-the-job-injury policy.)
- Create and foster an environment in the laboratory that encourages open discussion of biosafety issues, problems and violations of procedure.

2.6 Laboratory Staff

For the purposes of this discussion, whoever works in the laboratory in a technical (rather than purely administrative) capacity is defined as laboratory staff; this includes faculty members, students, interns, visiting scholars or volunteers.

Laboratory staff members are the most critical element in maintaining a safe working environment. Each person must consider their own safety and that of their co-workers. The laboratory staff's responsibilities include, but are not limited to the following:

- Conscientiously follow lab-specific biosafety and security practices and procedures.
- Be familiar with protocols and organisms used in the laboratory regardless of whether or not he/she works directly with them.
- Know all emergency procedures established by the Principal Investigator or laboratory director.
- Complete training and assure documentation of that training.

- Follow all appropriate laboratory practices as outlined in the Biosafety Manual and all additional practices outlined in the protocol and lab specific safety plan.
- Report to the PI, lab director, or lab supervisor all problems, violations in procedure, exposure events or spills as soon as they occur.
- Report to the Biosafety Officer any significant violations in biosafety policy, practices or procedures. No adverse action shall be taken against any person for reporting real or perceived problems or violations of procedures.

2.7 Liability Considerations

All faculty members and investigators should be aware of the potential for personal liability in performance of research and teaching involving biohazardous agents. The general rule of law that every individual is liable to others for negligent acts or omissions that cause injury to other persons is applicable to you and the work done under your direction. The rule applies whether a faculty member is working with a biohazard or pursuing other routine duties of teaching, research, and administration. **The increased potential for personal injury in a laboratory where persons are working with biohazardous agents is known or should have been known.**

To avoid injury and liability for injury, an investigator should exercise **due care** in research activities. What **due care** is, of course, will vary with the facts of a research situation. In everyday life activities, such as driving an automobile, the question to be asked in determining liability is whether a person acted as a reasonable person would have acted. In a laboratory setting, then, the question is whether the person **in charge** of research has behaved in a way that others with appropriate training and experience would have behaved. (One notable exception to the “reasonable man” standard is the principle of strict liability. Some activities have been judged to be so inherently dangerous that liability for injury attaches even in absence of negligence. Research with some biohazardous agents may fall into such a category of activities.) Whenever there is widely accepted procedure for handling materials or laboratory situations, that procedure usually will be the standard against which activities are measured. **Departures from written policies of an institution are also indications of a failure to exercise due care.**

As injuries are most likely to involve employees, the most important responsibilities of a principal investigator are **providing adequate instructions and supervision** to personnel handling biohazardous agents. The actual degree of instruction and supervision necessary in each case will depend upon the project and the degree of education and sophistication of the persons involved.

The University of Alabama at Birmingham is an agent of the State of Alabama, and administers a program of benefits for on-the-job injury. To promote efficient handling of claims or potential claims and to limit personal liability to the extent possible, all accidents or health problems related to work in a laboratory should be reported on an [Accident/Incident Report Form](#) according to instructions provided on the form.

2.8 Incidents of Non-compliance

Compliance with UAB, local, state, and federal safety regulations is required not only because of the need to conform to external regulations, but also to avoid endangering personnel, property, or the environment.

Incidents of non-compliance with campus Biosafety regulations or standards are usually discovered in the course of routine site visits by OH&S personnel or project review by the IBC. In most cases, these can readily be resolved through consultation by the PI or laboratory director with the Research Safety Coordinator’s staff, OH&S, and/or IBC. When more serious incidents arise, the IBC will review the incident, and based upon this review, which will include consultation

with the responsible investigator and/or laboratory director, will recommend corrective action to include the following:

- 2.8.1** The Institutional Biosafety Committee (IBC) is authorized by the President through the Vice President for Research to limit or suspend any research that is not in compliance with UAB Biosafety policies and procedures.
- 2.8.2** The Biosafety Officer, upon concurrence by the chair of the IBC or, in his/her absence, by at least three other technically qualified members of the IBC, may stop any work with microbial agents that creates a potential hazard to personnel, involves experiments prohibited by the institution, or violates regulations or policies. The entire Committee will then review the problem and forward written recommendations to the Vice President for Research for final action.
- 2.8.3** The Principal Investigator/Laboratory Director (PI/LD) and the IBC must concur on all matters relating to containment requirements, safe practices and handling procedures for biohazardous agents. The PI should submit a formal appeal to the IBC Chair stating noted differences along with data supporting his/her position. It may also be advantageous for the PI to meet with the IBC to assist in resolution of differences.
- 2.8.4** In the event of failure to concur, the recommendations of the IBC shall prevail until such time as concurrence can be reached or they are modified or rescinded by appellate decision of University officials. The IBC may refer questions relating to recombinant DNA/RNA studies to the NIH Office of Biotechnology Activities for final opinion.
- 2.8.5** When measures taken by the PI/LD are not sufficient to correct repeated noncompliance items and the PI/LD has not demonstrated any measure of intent to correct the reoccurring deficiencies, the Chair of the IBC may solicit assistance from the PI's Chair or Dean in resolving the noncompliance issues including recommending that the research be limited or suspended.
- 2.8.6** A PI/LD who has laboratory activities limited will lose the privilege to perform certain work with the agent for a designated time period to be determined by the IBC.
- 2.8.7** A PI/LD who has laboratory activities revoked will lose privileges to work with hazardous agents until adequate assurance is provided to the IBC that noncompliance items have been resolved.
- 2.8.8** Should the efforts of the IBC fail to gain compliance from the PI/LD, the Office of the Vice President for Research and/or the Office of the President will be contacted to assist in resolution of the situation.
- 2.8.9** The enforcement of safety measures instituted within a laboratory will ultimately rest with the PI/LD. Documented results of laboratory monitoring by OH&S will assist in determining the success of the program.
- 2.8.10** The IBC will provide reports to the Office of the Vice President for Research and/or the Office of the President to be forwarded to regulatory or funding agencies as appropriate.