

Chapter 1 Policy and Responsibilities

Policy

Responsibilities

Principal Investigator

Laboratory Workers

Department Heads

Institutional Biosafety Committee

The Vice President for Research

Policy

It is the policy of the University that all research and teaching involving potential biohazards be conducted in a safe manner in order to protect the academic community and the community at large.

The Institutional Biosafety Committee establishes local policy for review of all projects involving the use of recombinant DNA and microbial pathogens to assure compliance with the most current federal guidelines. Principal investigators at the University of Arizona who either store or carry out experiments involving recombinant DNA and microbial pathogens must inform the Institutional Biosafety Committee.

Further, it is University policy that no Class 4 Agents may be used or stored at the University of Arizona. See Appendix 1, NIH Guidelines, for a list of these agents.

Responsibilities

Principal Investigator

The Principal Investigator (PI) is defined as the faculty member in whose assigned space a research activity is conducted.

The Principal Investigator is responsible for full compliance with the policies, practices and procedures set forth in this Handbook. This responsibility extends to all aspects of biosafety involving all individuals who enter or work in the PI's laboratory or collaborate in carrying out the PI's research. Although the PI may choose to delegate aspects of the biosafety program in his/her laboratory to other laboratory personnel or faculty, this does not absolve the PI of the

ultimate responsibility. The PI remains accountable for all activities occurring in his/her lab. Documentation of training and compliance with appropriate biosafety practices and procedures is essential. The PI is responsible for assuring the appropriate safety training of employees and for correcting errors and unsafe working conditions.

1. General Responsibilities

As part of the general responsibilities, the Principal Investigator shall:

A. Attend the New PI Orientation class. If he or she is new to the UofA research community AND plans to work with recombinant DNA, microbial pathogens or human tissues, fluids or cell lines, visit the IBC table at this class. Classes are scheduled each fall. Call the Office of the Vice President for Research at 621-3512 for more information.

B. Develop and implement written laboratory-specific biosafety procedures that are consistent with the nature of current and planned research activities and are make available copies of the specific biosafety procedures in each laboratory facility. The PI shall ensure that all laboratory personnel, including other faculty members, understand and comply with these laboratory-specific biosafety procedures.

C. Delay initiation or modification of research governed by the Institutional Biosafety Committee (IBC) approval until that work, or the proposed modification, has been approved by the IBC.

See Appendix 2, Infectious Agents List, to determine biosafety levels. Refer to Chapter 3, Biosafety Level Practices Chart, for specific requirements associated with each biosafety level as well as Appendices 1 and 3 the NIH Guidelines for Recombinant DNA and the CDC-NIH Handbook for Biosafety in Microbiological and Biomedical Laboratories respectively, for information on biosafety practices and containment.

D. 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. It is essential that everyone who may have any potential exposure to biohazardous materials enter and/or work in the laboratory under the principle of Informed Consent.

E. Ensure that all maintenance work in, on or around contaminated equipment is conducted only after that equipment is thoroughly decontaminated by the laboratory staff or PI.

F. Ensure that research materials are properly decontaminated before disposal and that all employees are familiar with the different methods of waste disposal.

G. Report any significant problems, violations of the policies, practices and procedures set forth in this Handbook, to the Biosafety Office 621-3441.

H. Notify Risk Management & Safety (621-1790) immediately if a laboratory-acquired infection is known or suspected and report any significant research related accidents and illnesses within ten days (621-1790).

I. Be trained in standard microbiological techniques.

J. Ensure that all research personnel are appropriately trained in biosafety and receive appropriate medical surveillance when needed.

K. Develop (with the assistance of the IBC and Risk Management if requested) emergency plans for handling accidental spills and personnel contamination.

L. Create and foster an environment in the laboratory which encourages open discussion of biosafety issues, problems and violations of procedure. The PI will not discipline or take any adverse action against any person for reporting problems or violations to the IBC or Risk Management.

M. Comply with shipping requirements for biohazardous materials and select agents.

2. Submissions of Proposed Work to the Institutional Biosafety Committee (IBC)

The Principal Investigator shall:

A. Make an initial determination of the required levels of physical and biological containment in accordance with the requirements set forth in this Handbook.

B. Select appropriate microbiological practices and laboratory techniques to be used for the research.

C. Complete and submit a Memorandum of Understanding and Agreement (MUA) form to the IBC for review and approval.

D. Submit any significant changes in a given project to the IBC for review and approval. For example: i) work with mouse cells is changed to work with human or primate cells; ii) work begins with a new cell line that carries a potentially infectious organism; iii) work with a small part of an agent's genome is modified to working with $> 2/3$ of that genome; iv) change in animal species; v) change in host-vector system.

3. Prior to Initiating Research

The Principal Investigator shall:

A. Make available to all laboratory staff and involved facilities staff (such as animal care handlers) the protocols that describe the potential biohazards and the precautions to be taken.

B. Instruct and train all research personnel in: (i) the practices and techniques required to ensure safety and (ii) the procedures for dealing with accidents.

C. Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

D. Ensure that collaborators are made aware in advance of any biohazardous material sent to them, and comply with all applicable packaging and shipping requirements.

E. Maintain a log of all biological material received and sent. Logs should include the approximate quantity of the materials and where it is stored in the laboratory.

4. During the Conduct of the Research

The Principal Investigator shall:

- A. Supervise the safety performance of the laboratory staff to ensure that the required safety practices are employed.
- B. Investigate and report in writing to the IBC any significant problems pertaining to the operation and implementation of containment practices and procedures.
- C. Immediately notify Risk Management of any laboratory spills, accidents, containment failure or violations of biosafety practice which result in the release of biohazardous material and/or the exposure of laboratory personnel (or the public) to infectious agents. The IBC may be consulted by Risk Management if necessary.
- D. Correct work errors and conditions that may result in the release of biohazardous materials.
- E. Ensure the integrity of all containment systems used in the project.
- F. Restrict access as required by the laboratory-specific biosafety practices procedures and by the biosafety containment level approved by the IBC.

Laboratory Workers

Whoever works in the laboratory in a technical (rather than purely administrative) capacity is defined as a laboratory worker, whether the person is a faculty member, a student, an intern, a visiting scholar or a volunteer.

Laboratory staff are the most critical elements in maintaining a safe working environment. Each person must look out for their own safety and that of their co-workers. If individuals do not follow the university and laboratory-specific biosafety practices and procedures in the conduct of their laboratory duties, we cannot have a safe working environment. It is the laboratory staff's responsibility to:

- A. Conscientiously follow lab-specific biosafety practices and procedures.
- B. Inform the Principal Investigator of any health condition that may require additional safety precautions so that they can be put in place.
- C. Report to the Principal Investigator or the lab supervisor all problems, violations in procedure or spills as soon as they occur.
- D. Report to the Biosafety Office any significant violations in biosafety policy, practices or procedures which are not resolved by the Principal Investigator.
- E. Refuse to take any adverse action against any person for reporting real or perceived problems or violations of procedures to supervisors, the Principal Investigator, the Biosafety Office or members of the Institutional Biosafety Committee.

Department Heads

Department heads have the following responsibilities:

- A. Insure that prior to initiation of research, each investigator or laboratory director using recombinant DNA, microbial pathogens or human blood and tissues that may harbor a microbial pathogen, complete and file and IBC Memorandum of Understanding and Agreement (MUA) form.
- B. Insure that students have had instruction in safety procedures in teaching laboratories or field situations where the potential for exposure to a biohazardous agent or material exists.
- C. Determine that appropriate facilities and safety equipment are available for proposed research or instruction involving biohazardous agents.
- D. Provide leadership in laboratory safety at the management level in the department.

Institutional Biosafety Committee (IBC)

1. Charge of the Committee

The IBC is advisory to the Vice President for Research on all matters relating to the safe use of recombinant DNA and pathogenic microorganisms. It is the committee's responsibility to establish, monitor and enforce policies and procedures which meet or exceed applicable norms or regulations for recombinant DNA and pathogenic microorganisms. Any use of recombinant DNA, pathogenic microorganisms and mammalian cell lines must be reviewed and approved by the Committee. The Committee shall maintain diverse membership representing the community and a variety of University interests. Non-committee faculty or staff with special expertise will be asked to advise the Committee when the need arises.

2. Committee Membership and Procedures

A. The IBC is comprised of eighteen voting members, including four representatives from the community and State of Arizona. Also included are faculty representatives from the Campus Agricultural Center, the College of Law, the College of Medicine, Departments of Biochemistry, Ecology, Entomology, Molecular and Cellular Biology, Pediatrics, Plant Science, Plant Pathology and Veterinary Science and Microbiology.

IBC members are selected so that they have collective experience and expertise to fully evaluate the biosafety risks associated with the wide variety of research proposals which come under its scrutiny.

B. No member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he or she has been or expects to be engaged, or has a direct financial interest.

C. All projects of which an IBC member has an affiliation are reviewed by the Committee.

D. IBC meetings are normally held monthly during the academic year and as needed during the summer sessions.

3. Functions of the IBC

- A. Establish, monitor and enforce policy, practices and procedures for all work involving recombinant DNA, pathogenic microorganisms and mammalian cell lines at UofA. The IBC shall ensure adopted policies, practices and procedures meet applicable regulatory standards and guidelines.
- B. Review research conducted at or sponsored by UofA for compliance with adopted policies, regulations and guidelines. This review shall include an independent assessment of the containment required, and an assessment of the facilities, training and expertise of personnel involved in the research. The IBC shall ensure that the Principal Investigator is provided with the results of the review and determination of approval in a timely manner.
- C. Set required containment for research projects. The IBC will use the biosafety levels (BL) recommended by the CDC and NIH as the usual standards of containment to be set for work with a given biological agent. The IBC may, at its discretion, increase or reduce the BL depending on the circumstances presented by a specific project.
- D. Investigate any significant violation of policies, practices and procedures. The IBC will also investigate any significant research related accidents or illnesses. The IBC will determine and impose appropriate disciplinary action if an investigation reveals significant violations. The IBC will report its findings and actions to the Office of the Vice-President for Research, to granting agencies, and other regulatory agencies as required.
- E. Develop design specifications and criteria for containment facilities.
- G. Serve in an advisory capacity for research projects conducted at the Tucson Veteran Affairs Medical Center and the State Department of Agriculture.
- F. Perform such other functions as may be delegated to the IBC by the Vice President for Research.

The Vice President for Research

The Vice President for Research is responsible for ensuring that research is conducted in full conformity with the provisions of the references cited in Appendix 4. In order to fulfill this responsibility, the Vice President for Research shall:

- A. Establish and implement policies that provide for safe conduct of research and teaching involving biohazardous materials.
- B. Maintain an active Institutional Biosafety Committee.
- C. Through the IBC, ensure compliance with the regulations and guidelines by Principal Investigators conducting research at UofA.
- D. Direct that all projects shall include the necessary resources for the construction and operation of safe research and teaching facilities and for the implementation of the biosafety program.
- E. Provide adequate resources for the dissemination of information on biohazards and biosafety procedures, including training programs and workshops.
- F. Provide resources for medical surveillance measures to protect the health and safety of employees.

- G. Provide appropriate and sufficient legal protection for faculty and staff members who conduct activities in compliance with appropriate regulations and guidelines.
- H. Provide appropriate and sufficient legal protection for members of the IBC and its staff.

Quiz

1. The Institutional Biosafety Committee's main responsibilities include:
 - Establishment of policies for review of all projects involving the use of microbial pathogens and recombinant DNA.
 - Investigation of significant violations of policies, practices and procedures.
 - Review research conducted at or sponsored by the UA for compliance with adopted policies, regulations and guidelines.
 - All of the above.
2. A Principal Investigator wishing to have a proposal reviewed by the Institutional Biosafety Committee must fill out an on-line form at www.ibc.arizona.edu known as an:
 - Sponsored Projects Routing Sheet (PRS).
 - Memorandum of Understanding and Agreement form (MUA).
 - Certification of Safety and Health form (CSH).
 - None of the above.
3. From a research project management standpoint, the person who is ultimately responsible and accountable for compliance with biosafety is :
 - Vice President for Research and Graduate Studies
 - Department Head.
 - Laboratory manager.
 - Principal Investigator.
4. Laboratory worker's responsibilities include:
 - Conscientiously following lab-specific biosafety practices and procedures.
 - Informing Principal Investigators of all identified hazards before an exposure takes place.
 - Report to Biosafety Officer any significant violations in biosafety policies, practices or procedures not resolved by the Principal Investigator.
 - All of the above.
5. The Principal Investigator's responsibilities during the conduct of the research includes all but:
 - Supervising the safety performance of the laboratory staff to ensure that the required safety practices are employed.
 - Immediately notify Risk Management and Safety (RMS) if a laboratory-acquired infection is known or suspected.
 - Take immediate steps to terminate employees who report violations of UA biosafety practices.

- Create and foster an environment in the laboratory which encourages open discussion of biosafety issues and problem-solving techniques.
6. Biosafety Level 4 (BSL-4) agents must be approved directly by the Vice President for Research, before being shipped to campus.
- True
 - False
7. Before submitting a Memorandum of Understanding and Agreement form to the IBC, a Principal Investigator must:
- Make an initial determination of the required levels of physical and biological containment.
 - Select the appropriate microbiological practices and laboratory techniques used for the research.
 - Ensure that staff have been trained to identify specific biological hazards and know how to protect themselves through a combination of engineered control systems and laboratory practices.
 - All of the above.
8. The Institutional Biosafety Committee is advisory to the Vice President for research on all matters relating to the safe use of recombinant DNA and pathogenic microorganisms.
- True.
 - False.
9. In the case of a Post Doctorate employee conducting research in a lab space assigned to a Principal Investigator, the Principal Investigator is ultimately accountable for full biosafety compliance by the Post Doctorate employee.
- True
 - False
10. It is the overall policy of The University of Arizona that all research and teaching involving potential biohazards be conducted in a safe manner to protect the academic community and the community at large.
- True.
 - False.