

Appendix A: Stakeholder Roles & Responsibilities

The following section summarizes the roles and responsibilities of UTK administration, IBC members, research investigators, laboratory supervisors, and research personnel. Roles and responsibilities are appointed at the discretion of UTK administration and in accordance with the *NIH Guidelines* and other relevant regulatory standards, as well as UT System and UTK Campus policies relative to the employee [Code of Conduct](#), responsible conduct of research, and research integrity.

Designated Official

The UTK IBC is commissioned by and reports to a designated official (DO) as appointed by the UTK Chancellor. The DO is responsible for coordinating with applicable University administrators to ensure that research, teaching, diagnostic testing or other activities involving biological hazards are conducted safely and in compliance with applicable regulations, standards, and guidelines. In order to fulfill this responsibility, the DO shall:

- Establish and implement policies that provide for the safe conduct of research, teaching and diagnostic testing involving biological hazards.
- Maintain an active Institutional Biosafety Committee (IBC); appoint the IBC Chair, Vice-Chair and committee members in accordance with the *NIH Guidelines* and other university requirements as applicable.
- Grant the IBC and Biological Safety Officer (BSO) authority to oversee the safe and responsible use of biological hazards at the UTK-area campuses.
- Verify that all IBC-approved projects include the necessary resources for the construction and operation of safe research and for the implementation of the Biosafety Program.
- Appoint a Responsible Official (RO) to oversee the possession, use and transfer of CDC/USDA-listed Select Agents and Toxins (as applicable).
- Provide adequate resources for the dissemination of information on biosafety policies and procedures, including training programs and workshops.
- Coordinate or provide resources for medical surveillance measures or occupational health programs to protect the health and safety of faculty, staff, students, and visitors.
- Impose or uphold disciplinary actions or sanctions on principal investigators (PIs) or laboratory supervisors who fail to comply with established regulations, standards, guidelines, or university policies.
- Report any significant problems, or violations to U.S. Federal, State or local agencies as applicable. If appropriate, agency reporting may be delegated to the IBC or BSO.
- Represent the IBC as needed.

Institutional Biosafety Committee Members

The IBC Chair shall:

- Set meeting agendas and establish meeting dates.



- Conduct meetings.
- Prescreen submitted registrations as assigned.
- Approve registrations.
- Review and approve amendments and updates as necessary.
- Ensure member training; this task may be designated to the BSO or other qualified individual.

The Vice-Chair shall:

- Substitute for the Chair as necessary.
- Coordinate the periodic review and revision of the IBC Charter.
- Prescreen submitted registrations as assigned.
- Approve registrations in the absence of the Chair.

The IBC members shall:

- Complete biosafety regulatory awareness training (IBC training) before participating in voting activities of the committee. Complete annual retraining covering IBC-related topics as necessary.
- Attend monthly meetings; notify the IBC Chair if attendance is not possible.
- Prescreen submitted registrations as assigned.
- Review registrations and provide feedback to the IBC as necessary.

Biosafety Officer

The BSO is the primary intermediary between the IBC and PIs and/or laboratory supervisors. The BSO (and staff) shall:

- Manage the administrative tasks of the Biosafety Program and support implementation of IBC policies and procedures.
- At the discretion of the IBC, establish/implement a framework for oversight of biological hazards and associated procedures in teaching and diagnostic testing labs.
- At the discretion of the IBC, establish/implement a framework for oversight of regulatory permits (e.g. CDC, USDA APHIS, US FWS) and associated provisions.
- Administratively review proposals and protocols submitted by PIs and laboratory supervisors (as authorized by the IBC) and make recommendations to the IBC Chair.
- Develop and implement an exposure control plan for those research and teaching programs handling human derived materials as stipulated by the OSHA Bloodborne Pathogens Standard.

- Perform risk assessments and provide technical advice to the IBC, DO, and/or Select Agents RO as required or requested.
- Serve as an *ex officio* member of the IBC. If the university conducts research involving recombinant or synthetic DNA materials requiring BSL3 or BSL4 containment or engages in large-scale research or production involving viable organisms containing recombinant or synthetic nucleic acid molecules, then the BSO shall become a voting member of the IBC as per requirements of the *NIH Guidelines*.
- Assist PIs, laboratory supervisors, staff and students in conforming to applicable regulations, standards, guidelines and IBC policies by communicating expectations, providing training and technical advice, conducting facility inspections, and providing hands-on assistance as necessary (e.g., shipping biological materials).
- Perform annual inspections of facilities where biological hazards are being used or stored to ensure safety and containment measures as outlined in the *NIH Guidelines*, *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 5th ed.* (BMBL) manual, the OSHA Bloodborne Pathogens Standard, and/or other standards as applicable.
- Develop emergency plans for handling accidental spills and personnel contamination and investigate laboratory accidents involving biological hazards.
- Report any significant problems, violations, or research, teaching, or diagnostic testing-related accidents or illnesses to the IBC, DO, RO, or other campus administrators as applicable.
- Prepare periodic reports for institutional management regarding IBC activities and Biosafety Program status.
- Screen protocols submitted to the IACUC for identification of occupational hazards; consult with animal facility management, veterinarians and PIs regarding appropriate containment procedures for biological hazards. Employ a similar mechanism of review, assessment, and implementation for other UT compliance committees (e.g., human subjects research involving biological hazards submitted to the Institutional Review Board).

Select Agents Responsible Official

The RO is the University delegate with the legal authority and responsibility to oversee the possession, use and transfer of Select Agents. The RO is appointed by the DO, approved by applicable federal agencies, and charged with the legal authority and responsibility to oversee the possession, use and transfer of Select Agents. The RO shall:

- Possess a detailed knowledge of the Select Agent regulations to the extent that he/she can ensure the University is compliant with all of the programmatic requirements.
- Conduct annual inspections for each laboratory and all other registered areas where Select Agents are stored or used in order to determine compliance with the requirements of the Select Agent regulations. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected by specified date.
- Conduct annual emergency preparedness, spill response, and/or security drills as required.

- Have a physical presence at the University to maintain compliance with the Select Agent regulations and be able respond in a timely manner to onsite incidents involving Select Agents in accordance with the incident response plans.
- Be granted sufficient authority to speak and act on behalf of the University.

Principal Investigator

The PI is defined as the faculty member or other University employee in whose assigned space a research activity is conducted. The PI is accountable for all activities occurring in his/her lab and responsible for full compliance with applicable regulatory standards, guidelines and policies/procedures set forth by the University. In the context of this policy, the PI is primarily responsible for the prudent management of biological hazards and the safety and health of laboratory staff, students, volunteers, and visitors. Although the PI may choose to delegate these aspects to other laboratory personnel or faculty, this does not absolve the PI of his/her ultimate responsibility. The PI shall:

- Create and foster an environment in the laboratory that encourages open discussion of biosafety issues, problems and violations of procedure. Per Tennessee State labor laws and University policies (e.g. [HR0580, UT Code of Conduct](#)), the PI will not discipline or take any adverse action against any person for reporting problems or violations to the IBC, BSO, DO, Risk Management, or State or Federal agencies.
- Comply with all regulations, standards, guidelines and University policies involving handling, storage, disposal, inventory, security/access, and transportation of biological hazards.
- Develop, implement, and maintain written laboratory-specific biosafety procedures appropriate for the biological hazards used in the laboratory. The PI shall ensure that all laboratory staff, students, and visitors understand and comply with these laboratory-specific biosafety procedures.
- Delay initiation of research involving biological hazards (including recombinant and synthetic nucleic acids) until the research protocol has been submitted to, reviewed, and approved by the IBC or BSO as required.
- Maintain an inventory of all biohazards used or stored in the laboratory. Logs should include species/strain-specific details, approximate quantity on hand, and where they are stored in the laboratory.
- Restrict access to the laboratory and stored biological hazards to authorized personnel only.
- Ensure that all laboratory personnel, maintenance personnel and visitors who may be exposed to any biological hazards are informed in advance of the potential risk and of the practices required to minimize that risk.
- Add staff, students, and visitors working on IBC-approved projects to the respective IBC registration(s). Regularly review listed personnel and provide updates to the IBC or BSO as applicable.
- Complete training as required by the IBC or any other oversight agency, ensure that all staff, students, and visitors participating in biohazard related activities have completed appropriate training, and maintain documentation of training. The PI or designee must provide protocol-, agent- and laboratory-specific training. The PI should contact the BSO for assistance with all biosafety training needs.



- Supervise the performance of the laboratory staff to ensure that required safety practices are employed. Work errors and conditions that may result in accidental releases or exposures are to be corrected immediately.
- Provide and maintain all personal protective equipment (PPE) designated by risk assessment, including routine cleaning and/or replacement of dirty or contaminated PPE as appropriate. Additionally, the PI shall ensure that all affected laboratory faculty, staff, students, and visitors wear PPE as prescribed.
- Ensure that all safety and containment equipment is maintained in good condition and functionally verified as necessary. Maintenance work in, on or around contaminated equipment is to be conducted only after that equipment is thoroughly decontaminated by the laboratory staff or PI.
- Properly segregate and decontaminate biohazardous wastes before final disposal. All laboratory faculty, staff, and students are to be familiar with the appropriate methods of waste disposal.
- Coordinate with the BSO to develop emergency plans for accidental spills and exposures.
- Immediately notify the BSO of any laboratory spills, accidents, containment failure or violations of biosafety practices that result in the release of biological hazards and/or the exposure of laboratory personnel (or the public). The IBC may be consulted by the BSO as necessary.
- Inform affected personnel of signs/symptoms that may result from accidental exposures and ensure that they are informed of and receive medical surveillance or occupational health reviews as necessary.
- Immediately notify the BSO if a laboratory-acquired infection is known or suspected, or if a spill of any quantity involving an agent infectious to humans, plants, or animals occurs in a public area.
- Comply with shipping and permit regulations for biological hazards. The BSO conducts shipping training for affected PIs and personnel as necessary. The PI should contact the BSO to ensure that all applicable transportation safety regulations have been met prior to shipping microbiological cultures, tissues (human or animal) or body fluids.
- Immediately notify the BSO if a Select Agent or other high-consequence pathogen (i.e. Risk Group 3 or 4) has been isolated and confirmed from environmental and/or diagnostic specimens.

Laboratory Supervisor

The laboratory supervisor is the individual (faculty member or departmental designate) with primary responsibility for the use of biological hazards in the University's teaching or diagnostic testing laboratories. The laboratory supervisor shall:

- Comply with all regulations, standards, guidelines and University policies involving handling, storage, disposal, inventory, security/access, and transportation of biological hazards.
- Register biological hazards with the IBC or BSO (as designated).
- Complete training, and ensure that all teaching or diagnostic testing staff have completed training, as required by the IBC or any other oversight agency as applicable. Comparable information or training materials should be

provided to students and trainees. Training and/or distribution of training materials should be documented by the laboratory supervisor.

- As necessary, communicate to teaching or diagnostic testing staff and students/trainees the signs and symptoms which may result from accidental exposures to the biological hazards in use.
- Stipulate the safety precautions to be followed by teaching or diagnostic testing staff, students, and trainees and ensure that these are followed. Work errors and conditions that may result in accidental releases or exposures are to be corrected immediately.
- Determine the proper PPE to be worn for designated procedures. The laboratory supervisor (or designate) shall ensure that PPE is worn as directed and cleaned/replaced as appropriate.
- Immediately notify the BSO of any laboratory spills, accidents, containment failures, or violations of biosafety practice which result in the release of biological hazards and/or the exposure of laboratory personnel or students/trainees. The IBC may be consulted by the BSO as necessary.
- Immediately notify the BSO if a laboratory-acquired infection is known or suspected, or if a spill of any quantity involving an agent infectious to humans, plants, or animals occurs in a public area.

Department Head

The Department Head shall:

- Review and approve IBC registrations submitted by departmental faculty members.
- Verify that appropriate facilities are available to control biological hazards.
- Verify that the PI or teaching lab supervisor has competency commensurate with the proposed project and/or assigned laboratory course(s).
- Ensure that any reported safety deficiencies or compliance concerns/violations are corrected by the PI or teaching supervisor in a timely fashion.
- Notify the BSO of new faculty hires, preferably before the new PI arrives on campus, if he/she plans to work with biological hazards.
- Notify the BSO/IBC if a PI can no longer carry out his/her responsibilities (e.g. leaves the University, retires, etc.). If this is the case, the Department Head must select one of the following actions within 30 days of the PI's departure:
 - Assume responsibility for a PI's registration(s) and manage it under his/her own program. This change in proprietorship must be reported to the BSO/IBC, and the Department Head must comply with all IBC provisions; or
 - Assign the registration(s) to another investigator. This change in proprietorship must be reported to the BSO/IBC, and the designated PI must comply with all IBC provisions; or

- Inactivate/destroy the registered materials and terminate the registration.
- Ensure that the PI and/or designated staff follow laboratory commissioning/decommissioning procedures (see [EHS LS-003 Guide](#)), including the appropriate disposal of biological hazards and disinfection of affected surfaces and equipment.

Laboratory Personnel

Laboratory personnel (staff, students, volunteers) shall:

- Participate willingly in biosafety orientation and training programs offered by the University.
- Become familiar with lab-specific biological hazards.
- Abide by all biosafety precautions that are relevant to the assigned duties.
- Use prescribed personal protective equipment directed by the supervisor and in accordance with proper biosafety precautions.
- Report any observed unsafe conditions and unsafe practices to the University administration (e.g. PI/laboratory supervisor, department head, dean or associate dean, BSO, IBC Chair, or DO).
- Exercise good judgment and ask questions regarding lab practices where you question the level of risk.
- Look out for the safety of others in the lab and lab facilities.

