

Institutional Biosafety Committee - Charter and Bylaws

Approved November 2022

Authority

The University of Tennessee at Chattanooga (UTC) is required to establish and commission an Institutional Biosafety Committee (IBC) for the oversight of recombinant and synthetic nucleic acid research in accordance with the [National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#) (*NIH Guidelines*). Additional areas of oversight may be included at the institution's discretion. The UTC IBC is commissioned by and reports to a designated official (DO) as appointed by the UTC Chancellor. The DO, in collaboration with other Chattanooga-area stakeholders:

- Ensures that the IBC is appointed in accordance with the *NIH Guidelines*.
- Establishes the scope, purview, and core objectives and responsibilities of the committee and associated biosafety program in accordance with the *NIH Guidelines*, UT System biological safety policy (SA0450), and other relevant regulations and policies.
- Provides appropriate resources to support and sustain the core objectives and responsibilities of the committee and associated biosafety program.

Mission, Scope, and Purview

The IBC is committed to protecting faculty, staff, students, visitors, the general public and the environment from potential and actual exposures to biological hazards, and to ensuring that activities involving biological hazards and the facilities used to conduct such work are in compliance with applicable U.S. Federal, Tennessee State, and local laws, regulations, and guidelines. The IBC defines biological hazards as the following:

- Recombinant nucleic acid molecules or synthetic nucleic acids as defined in [Section I in the NIH Guidelines](#), including transgenic plants and animals.
- Biological agents (bacteria, viruses, fungi, protozoa, parasites, and prions) and/or vectors that carry biological agents (arthropods, snails, etc.) which: 1) cause or are reasonably expected to cause disease in immunocompetent humans; or 2) cause or are reasonably expected to cause significant disease in local livestock (including poultry), agricultural crops, or indigenous wildlife; or 3) otherwise require containment and safeguards at biosafety level (BSL)-2 or higher.
- Acute biological toxins having an LD50 < 100 ng/kg in mammals and/or those listed as Select Toxins (Department of Health & Human Services). *Note: UTC currently lacks adequate containment facilities to support such activities.*
- Human or nonhuman primate blood, blood products, unfixed tissues/organs, secretions, excretions, or cell lines unless documented to be free of bloodborne pathogens or are otherwise low risk as per written risk assessment.
- Venomous animals posing a risk to humans through bite or sting and housed and/or manipulated in laboratories or other indoor facilities (e.g., greenhouses).
- Poisonous plants posing a risk to humans via dermatological contact, inhalation, or other route of exposure and housed and/or manipulated in laboratories or other indoor facilities (e.g., greenhouses).
- Novel nanoparticles conjugated to biologically active or cell-modifying molecules.

- Diagnostic specimens or environmental samples likely to contain any of the above and posing a significant risk to humans or local livestock (including poultry), agricultural crops, or indigenous wildlife as per documented risk assessment, including materials requiring a federal or state permit (e.g., foreign soils, noxious weeds, etc.).

IBC oversight applies to research, teaching, diagnostic testing and other activities conducted at, sponsored by, or on behalf of the Chattanooga campus.

Exclusions to the purview of the IBC:

- Allergens, zoonoses, and other biological risks associated with the routine care and use of research or teaching animals are deferred to the Institutional Animal Care & Use Occupational Health Program. (Note: research, teaching, and diagnostic testing involving zoonotic agents are subject to IBC oversight as described above).
- Use/exposure to human blood, tissues, and body fluids external to research, teaching, or diagnostic testing settings (e.g., medical/first aid, law enforcement, facilities maintenance, athletics, custodial services, etc.) is deferred to the respective UTC Safety and Risk Management general/occupational safety policies and procedures.
- UTC University Health Services patient clinics and procedural areas are deferred to the respective administration's oversight.

IBC Responsibilities and Objectives

The primary objective of the IBC is to ensure the safe, responsible, and compliant management of biological hazards used in research, teaching, and diagnostic testing. In an effort to achieve that objective, the UTC IBC will:

- Establish, communicate, and monitor policies, practices, and procedures covering biological hazards which are in accordance with applicable regulatory standards and guidelines.
- Review biological hazard registrations to ensure compliance with regulations, guidelines, and adopted policies. Review will include an independent assessment of the risk(s), required safety practices, biological/physical containment and associated facilities, and training and expertise of affiliated personnel. The IBC will communicate registration review outcomes and necessary actions to the principal investigator (PI) or laboratory supervisor in a timely manner.
- Regularly assess safety practices and containment facilities to ensure they are appropriate for the proposed biological hazards and affiliated procedures. The IBC will use the biosafety levels published by the CDC, NIH, and USDA as the usual standards of containment to be set for work with a given biological agent. To the extent allowed by Federal law and regulation, the IBC may, at its discretion, increase or reduce the BSL depending on the circumstances presented by a specific project.
- Investigate and recommend corrective actions for accidents, exposures, illnesses, environmental releases or other adverse events involving biological hazards. The NIH Office of Science Policy (OSP), CDC, USDA, or other regulatory or funding agencies will be notified if required.
- Investigate and set corrective actions for violations of policies, safety practices, or procedures. The IBC, at its discretion, may deny, suspend, or terminate approval for use of biological hazards if such use poses a risk to personnel or public health and safety, or for issues of noncompliance. If necessary, recommendations for additional disciplinary actions may be made to UTC

administration. The NIH Office of Science Policy (OSP), CDC, USDA, or other regulatory or funding agencies will be notified if required.

- Review and assess compliance with permit or license-related requirements for biological materials subject to USDA APHIS, FDA, and/or EPA regulations.

Membership

Membership of the IBC is based on the [NIH Guidelines \(section IV-B-2-a\)](#). Members are appointed by the designated official for a renewable term of three years. New committee members may be recommended by current members or research administrators. An effort is made to represent all major units served, to have a mix of tenured and non-tenured faculty, to have collective expertise to cover the scope and purview, and to represent the diversity of the university community. Committee composition will be reported annually to the NIH Office of Science Policy as required. The committee generally includes voting members and ex officio non-voting members as follows:

- Voting members:
 - Committee Chair
 - Committee Vice-chair
 - Plant containment expert
 - Animal containment expert
 - At least 2 members with no affiliation to the university and who represent the interest of the surrounding community with respect to health and protection of the environment
 - One or more faculty members from each department that conducts activities involving recombinant and/or synthetic nucleic acids (e.g., Biology, Geology and Environmental Science; Chemistry and Physics; Civil and Chemical Engineering)
 - Laboratory technician or other technical staff member
- *Ex officio* (non-voting) members:
 - Designated Official
 - Biosafety representative from UTC Safety and Risk Management
 - Biosafety staff at the discretion of the IBC
- Ad hoc subject matter expertise: if a registration or topic falls outside the expertise of IBC members, the IBC Chair is authorized to seek counsel from an individual knowledgeable in the subject matter. This person(s) can be someone external to the university as necessary.

IBC members are expected to attend and participate in meetings. Members will be advised to notify the Chair, Vice-Chair, or Designated Official if they will be absent from the upcoming meeting(s). Members who will miss a meeting may share their notes and comments with the Chair, Vice-Chair or Designated Official; however, they cannot cast an absentee vote or vote by proxy.

Stakeholder Roles & Responsibilities

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

Designated Official

The UTC IBC is commissioned by and reports to a Designated Official (DO) as appointed by the UTC 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. 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 authority to oversee the safe and responsible use of biological hazards at UTC.
- Verify that all IBC-approved projects include the necessary resources for the design and operation of safe research and for implementation of the Biosafety Program.
- 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 as mandated in applicable regulations.
- 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 Chair.
- 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.
- Coordinate the periodic review and revision of the IBC Charter.
- Ensure member training; this task may be designated to Office of Research Integrity staff.

The **Vice-Chair** shall:

- Substitute for the Chair as necessary.
- Prescreen submitted registrations as assigned.
- Approve registrations in the absence of the Chair.

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.
- Verify that PIs or teaching lab supervisors have competency commensurate with the proposed project and/or assigned laboratory course(s).

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, 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 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 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 IBC or DO 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 IBC to develop emergency plans for accidental spills and exposures.
- Immediately notify the UTC Police Department 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 UTC Police will contact the IBC Chair, DO, and/or Director of Safety and Risk Management as appropriate.
- 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 UTC Police Department, IBC Chair and DO 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 Office of Research Integrity provides shipping training for PIs and personnel as necessary. The PI should contact the Director of Safety and Risk Management 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 IBC Chair and DO 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 designee) 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.
- 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 UTC Police Department 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 students/trainees. The UTC Police will contact the IBC Chair, DO, and/or Director of Safety and Risk Management as appropriate.
- Immediately notify the UTC Police Department, IBC Chair and DO 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.
- Coordinate with the IBC to confirm that appropriate facilities are available to control biological hazards.
- Ensure that any reported safety deficiencies or compliance concerns/violations are corrected by the PI or teaching supervisor in a timely fashion and communicated to Safety and Risk Management.
- Notify the IBC of new faculty hires, preferably before the new PI arrives on campus, if he/she plans to work with biological hazards.
- Notify the 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 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 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, 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, Safety and Risk Management, 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.

Training

Prior to committee service, all IBC members will complete training covering the *NIH Guidelines* and other applicable regulations and guidelines, including: NIH review categories, risk assessment, risk groups, biosafety levels, laboratory-acquired infections, and risk management and safety practices. Refresher or topical training will be provided at least annually. IBC member training will be documented.

Committee Meetings

The UTC IBC will be scheduled to meet on a monthly basis. Meetings may be added or canceled according to registration review volume or special circumstances. A meeting calendar will be maintained on the UTC Biosafety Program website. Usually, meetings are open to the public and are announced on the UTC Biosafety Program website (and other outlets as necessary). However, the IBC, at its discretion, may close the meeting, or part of a meeting, consistent with protection of privacy; proprietary interests; health and safety of university employees, the environment, and the community; or as required by law or regulation.

Agendas

Agendas are prepared by the IBC Chair in collaboration with the DO or the DO's designee and distributed to the committee approximately one week in advance of a scheduled meeting. However, sudden changes in circumstances or emergency events may require an updated agenda at the meeting. Agendas will include a review of the previous meeting's minutes, registrations (or amendments) called to full committee, old business recaps or updates, and new business items. Any IBC member may request an item to be included on the agenda.

Proceedings

All meetings will be held in person or other live interactive format (e.g., video conference). Meetings will be conducted in accordance with Robert's Rules of Order. The Chair will issue all points of order,

summarize initiatives as necessary, moderate discussion, and call for motions. Motions, seconds, and/or other propositions may be made by any voting member of the IBC.

Review outcomes and recommendations will be reported in writing to registrants in a timely manner. Likewise, where meeting outcomes create (draft) changes in policy or (draft) changes in procedure that affect research, teaching or diagnostic testing operations, the changes will be communicated promptly to the affected constituencies. The communication mechanism may vary due to circumstances and/or needs, but will generally include electronic distribution via e-mail, campus distribution lists, or the UTC Biosafety Program website.

Quorum and Voting Rights

A quorum for a meeting will be a simple majority of the voting membership, including at least one non-affiliated representative. Approval of registrations, policies, or other resolutions may be granted by a simple majority of committee members attending a meeting.

Conflicts of Interest

A conflict of interest is defined as financial involvement with a commercial sponsor or personal relationship with an investigator or a sponsor. The University's conflict of interest policy is published in the University's fiscal policies ([policy number GE0002](#)). Any IBC member with financial or other interests involving the investigator or a research sponsor should inform the IBC and, if necessary, follow the procedures in the policy to manage or resolve the conflict, if any. All members, including non-affiliated representatives, should have an Outside Interest Disclosure form on file with the University. Committee members may participate in discussion but must abstain from voting on registrations associated with the conflict of interest.

Ad Hoc Subcommittees

Ad hoc subcommittees may be established as necessary to address particular matters related to biological hazard use or associated oversight. The composition, scope, and duration of such a subcommittee will be determined by the committee leadership. Subcommittees may be composed solely of members from the UTC IBC or may include non-members, as determined by the committee leadership.

Minutes

Minutes of the meeting shall include: the time, date and location of the meeting; a copy of the meeting agenda; a list of members present and members absent; notes about the sequence of items discussed; the substance of the discussions, including any concerns and respective resolutions; NIH review categories (where appropriate); vote outcomes; approved biosafety level(s); and any action items and responsible parties. Minutes shall be:

- Taken by an Office of Research Integrity staff member.
- Provided approximately one week before the next meeting and reviewed at the beginning of that meeting for correction and/or approval.
- Maintained on the UTC Biosafety Program website at a weblink for the UTC IBC.
- Accessible to the public (note: in rare cases, the IBC may redact sensitive or proprietary information prior to posting to protect the university's interests).

Non-disclosure

Section 8 of the [University's Code of Conduct](#) requires that all employees protect the confidentiality of information that they receive in the course of their employment, as required by applicable laws, contracts, and policies:

Responsible Use and Protection of Confidential Information: Employees are entrusted with a variety of confidential information about students, faculty, staff, alumni, donors, research sponsors, licensing partners, patients, and others. Employees must access, use, protect, disclose, preserve, and dispose of confidential information in compliance with applicable laws, regulations, contracts, and university policies.

Specific non-disclosure agreement requests made by granting agencies, corporations, other commercial entities or individuals will be submitted to the Office of Research and Sponsored Programs for review by the Office of Research Integrity and/or Office of the General Counsel, as appropriate.

Protections against Liability for IBC Members

The University provides legal protection against liability for its employees in the conduct of their job functions. State law, Tenn. Code Ann. §9-8-307(h), provides that state employees, including employees of The University of Tennessee, have immunity from liability for acts or omissions within the scope of their employment, unless the acts or omissions are willful, malicious, criminal, or done for personal gain. The full policy may be viewed at: <https://counsel.tennessee.edu/liability/>. For more information on University Employee Protections against Liability, contact the Office of the General Counsel.

Non-employees on the IBC (i.e., non-affiliated members) are encouraged to become a “registered volunteer” by contacting the UTC Office of Research Integrity (ori@utc.edu). A registered volunteer is defined as a person who is not an employee of the University but provides service to the University in an approved program. Registered volunteers are reported to the Division of Claims Administration, State of Tennessee and receive the same civil immunity from liability as University employees under the Tennessee Claims Commission Act (note: volunteers under the Claims Commission Act are not covered for Worker’s Compensation).

Charter Acceptance and Revision

The UTC IBC charter will be reviewed at least every three years but may be reviewed more frequently as necessary. Acceptance of the Charter and any future revisions must be approved by the voting members of the IBC and the designated official. A two-thirds majority of the voting membership of the IBC is required to accept the charter and any revisions to the document. This vote may be submitted by a written proxy if necessary.