A PURPOSE

This SOP describes the registration, reporting, review, and recordkeeping procedures for research and teaching activities involving biological hazards.

B POLICY

The IBC requires documentation of biological hazards used in research and teaching as well as associated procedures for the receipt, storage, use, transfer, and disposal of hazardous materials. Principal investigators, laboratory course instructors, and/or laboratory supervisors (hereafter collectively referred to as "PIs") are expected to register and regularly update their biohazard inventory, handling procedures, laboratory infrastructure, and personnel. Documentation is reviewed by the IBC and by supporting staff at the IBC's discretion and as allowable by regulatory standards. Registrations, reports (protocol amendments and updates), and supporting materials such as training records, material transfer agreements, equipment validations, regulatory permits, etc. will be maintained and managed by the Office of Research Integrity.

C REGISTRATION PROCEDURE

PIs must register research and teaching activities involving biological hazards using the IBC Registration Form provided on the IBC website. Required information includes: laboratory location and biosafety level, types of biological hazards used, applicable risk group(s) and/or *NIH Guidelines* review categories, work practices and containment plans, emergency procedures, occupational health requirements, and personnel training confirmation.

- Registrations for teaching laboratories using biological hazards can be submitted by the instructor or laboratory supervisor. For multiple sections of a given course, all instructors who teach the course can be listed on a single registration form if the biohazards used in all lab sections of the course are identical.
- Federal or state-issued permits/authorizations (e.g., USDA, APHIS, CDC) for the receipt and use of biological hazards may be substituted for an IBC registration at the discretion of the IBC.

D REPORTING PROCEDURE—AMENDMENTS & UPDATES

Amendments and updates to IBC registrations are made using the IBC Registration Amendment/ Update Form provided on the IBC website.

Amendments to registered biohazards (including recombinant or synthetic nucleic acid [rsNA] molecules), handling procedures, laboratory infrastructure, and personnel must be reported to the IBC so risk assessments and review/approval requirements can be determined in a timely fashion. In some cases, the IBC may require submission of a new registration (if the research scope deviates

from that in the approved registration) and/or preapproval (if the amendment results in changes to the *NIH Guidelines* review category and/or biosafety level).

PIs are required to complete an annual update for active registrations. Annual updates capture project status (if applicable), any changes to biohazards, procedures, facilities, or personnel, as well as any accidents/injuries/exposures not previously reported to the IBC.

Failure to Register/Report

Failure to register and/or willful neglect of reporting requirements is subject to IBC noncompliance procedures. Administrative actions for unresolved noncompliance may include the total shutdown of a lab or office; referral of the responsible individual for disciplinary action; reporting to local, state or federal regulatory and/or funding agencies; and suspension of research.

E REVIEW PROCEDURES

IBC registrations, amendments, and updates are routed and reviewed as follows:

1. The IBC Coordinator assigns a registration number (for new registrations) and performs a pre-review to verify form completion and identify omissions or information inconsistencies.
2. The IBC Coordinator communicates pre-review action items to the PI.
3. The PI addresses action items and submits a revised version of the registration form.
4. The IBC Coordinator alerts the IBC Chair and routes the registration to full committee review (FCR) or Administrative Review depending on the following criteria:
    - FCR requires review/approval by the full committee and is required for the following:
        - Initial registration of non-exempt recombinant and synthetic nucleic acids (rsNA)
        - Initial registration of infectious agents affecting human health
        - Initial registration of acute biological toxins (LD_{50} < 100 ng/kg) or select agent toxins
        - Amendments/updates involving rsNA and resulting in a change of the *NIH Guidelines* review category
        - Initial registration of field procedures involving biohazards (or potential exposures to biohazards)
        - Initial registration of nanoparticles conjugated to biologically active or cell-modifying molecules
        - Initial registration of activities involving venomous animals
        - Initial registration of activities involving poisonous or psychotropic plants
        - Amendments/updates that involve safety/containment changes
    - Administrative Review may be conducted by the IBC Chair (Vice-Chair) at the discretion of the IBC for the following:
        - Initial registration of exempt rsNA activities

- Initial registration of human-derived materials
- Initial registration of primary diagnostic samples from animals and humans
- Microbial identification/enumeration from diagnostic or environmental samples
- Amendments/updates that do not alter the *NIH Guidelines* review category (for rsNA) or do not involve safety/containment changes (e.g., conservative changes to vectors/inserts, personnel updates, equipment updates, etc.)

Submissions reviewed by AR may be called to full committee review by the IBC Chair (Vice-Chair) at their discretion. Approvals granted by Administrative Review will be disclosed to the full committee at the subsequent meeting.

5. Review may result in one of the following decisions:
   - Approved as submitted or with minor revisions/contingencies pending administrative confirmation
   - Major revisions requested; registration tabled until next scheduled FCR
   - Not approved due to unacceptable risk to health/environment, inadequate containment facilities, lack of training/expertise, etc.
6. Upon verification of revisions (as necessary), the registration is routed to the PI's Department Head for approval confirmation. If the Department Head remains unresponsive after three weekly reminders, the registration is routed to the Associate Dean of the PI's College for approval confirmation.
7. Upon confirmation of approval, the IBC Coordinator generates an approval letter and sends it to the PI, IBC Chair (Vice-Chair), and Department Head. Approvals are valid for three (3) years from the start date noted in the registration form, contingent upon annual updates as described above. A flow diagram of the IBC review process is provided in Appendix A.
8. If a registration cannot be approved, the IBC Chair will communicate the review outcome and rationale to the PI, Department Head, and the Designated Official.

F RECORDKEEPING PROCEDURES

IBC records are maintained by the Office of Research Integrity. Data management and security will follow the University of Tennessee at Chattanooga's policies, procedures, and general oversight framework. Records will be maintained for a minimum of three years beyond the registration's expiration/termination date or for the duration mandated by applicable regulations (e.g., OSHA Bloodborne Pathogens training documentation requirements), whichever is most conservative.

G CONTACTS

Dr. David Giles
IBC Chair
Associate Professor
Department of Biology, Geology and Environmental Sciences

350J Holt Hall, Dept. 2653
615 McCallie Avenue
Chattanooga, TN 37403
(423) 425-2781
ibc@utc.edu

Dr. Cheryl Murphy
Designated Official for UTC Biosafety Program
Director, Office of Research Integrity
109 Race Hall, Dept. 4915
615 McCallie Avenue
Chattanooga, TN 37403
(423) 425-4443
ibc@utc.edu

UTC Institutional Biosafety Committee SOP #1, Appendix A:

IBC Review Process Flowchart