

THE UNIVERSITY OF TENNESSEE
Knoxville

Institutional Biosafety Committee Charter and Procedures

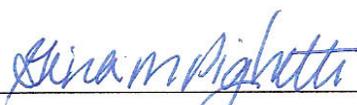
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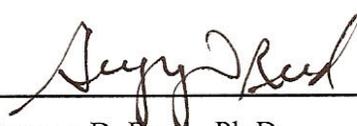
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APPROVALS PAGE

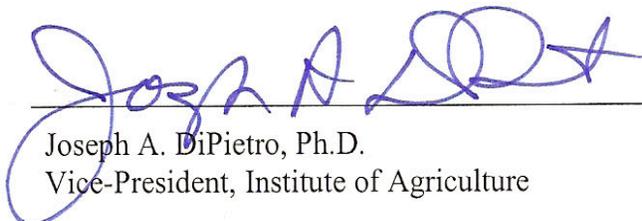
The Institutional Biosafety Committee of The University of Tennessee has voted to accept this document as its Charter. In addition, the Administration, represented by the signatories below has also accepted this Charter.



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Associate Professor, Animal Science



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Associate Vice Chancellor for Research
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Vice-President, Institute of Agriculture



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Dean, Knoxville Graduate School of Medicine
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I. FUNDAMENTAL POLICY STATEMENT

It is the policy of the Institutional Biosafety Committee (IBC) of The University of Tennessee, Knoxville (UT) that the Principal Investigator (PI), the Department Head, and the Laboratory Director or Supervisor are responsible for the safe handling of biohazardous agents, including recombinant DNA molecules, in their facilities. The policies of UT follow guidelines and regulations set forth by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA).

II. WHAT FOLLOWS

This document describes the current policies of the IBC for the Knoxville units of the University (see Section IV, A of this Charter) and its role in ensuring that research involving biohazardous agents is conducted in a manner that is safe for staff, the general public and the environment. This document is intended to define the role of the IBC and help administrators, PIs, and IBC members comply with applicable Federal, State of Tennessee, City of Knoxville, and University guidelines and regulations.

III. BACKGROUND

Responding to public concerns about the effects of recombinant DNA technology, the National Institutes of Health established a Recombinant DNA Advisory Committee (RAC) in late 1974. The RAC was given authority to govern recombinant DNA research at all NIH funded institutions. In 1976, the RAC published a set of research guidelines entitled “NIH Guidelines for Research Involving Recombinant DNA Molecules” (*NIH Guidelines*). The purpose of the *NIH Guidelines* is to specify practices for constructing and handling (i) recombinant DNA molecules and (ii) organisms and viruses containing recombinant DNA molecules. Compliance with *NIH Guidelines* is mandatory for any institution that receives funding from NIH. Furthermore, the institution must ensure that all research involving recombinant DNA conducted at or sponsored by the institution, irrespective of the source of funding, is in compliance with *NIH Guidelines*. In accordance with *NIH Guidelines*, the institution must establish or utilize a local IBC with the authority to enforce the guidelines. An IBC is composed of members of the institutional staff and community representatives.

In 1977, The University of Tennessee established an *ad hoc* Biohazard Safety Committee. The charge of the committee was to:

1. Develop a Biohazard Manual
2. Identify existing biohazards at The University of Tennessee, Knoxville campus.
3. Review, inspect, and monitor all individuals and facilities that use biohazardous agents in both research and teaching.

4. Review all extramural and intramural research proposals for the purpose of identifying those involving the use of biohazardous agents.
5. Function as an in-house entity and not broadly disseminate deliberations of the committee.

Specifically, these responsibilities included review of biological research for the Colleges, Schools, and Institutes of the Knoxville campus and the UT Memorial Research Center (now UT Graduate School of Medicine).

In 2004, the administration of the Knoxville campus, the Institute of Agriculture, and the Graduate School of Medicine added a full-time Biological Safety Officer (BSO) position to the Office of Research in order to assist the IBC and the research community in meeting the compliance requirements of the *NIH Guidelines*. The BSO is also responsible for the development, implementation and maintenance of a comprehensive Biosafety Program. The IBC and its policies will complement and support the objectives of this Biosafety Program.

IV. RESPONSIBILITIES

A. IBC

The IBC serves The University of Tennessee, Knoxville (UTK), UT Institute of Agriculture (UTIA), and the UT Graduate School of Medicine (UTGSM). Hereinafter these units will be collectively designated as UT. The IBC reports to the Associate Vice-Chancellor for Research in the UT Knoxville Office of Research. Administrative tasks of the IBC are processed by staff at the Biosafety Office and/or the Office of Research.

The IBC establishes, recommends, and/or approves policies on the proper use of biohazardous agents including, but not limited to: recombinant DNA molecules, infectious agents, acute biological toxins, and venomous animals/poisonous plants. Policy objectives are to protect staff, research subjects, the general public, and the environment from biohazardous agents. In the unlikely event that a laboratory persists in following procedures in violation of compliance regulations and IBC policies, the Committee will recommend the imposition of sanctions by Department Heads and Deans.

The IBC shall:

1. Establish and monitor policy, practices and procedures for work involving biohazardous agents at UT.
2. Ensure that adopted policies, practices and procedures for work with biohazardous agents meet applicable regulatory standards and guidelines.
3. Review biological research conducted at or sponsored by UT for compliance with adopted policies, regulations and guidelines. This review shall include an independent assessment of the biological containment required, and an assessment of the facilities, training and expertise of personnel involved in the research. The IBC shall ensure that the PI is provided with the results of the review and determination of approval in a timely manner.

4. Assess proposed containment facilities and practices for research projects. The IBC will use the biosafety levels (BSL) 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.
5. Review any findings of the BSO in investigating any significant violation of policies, practices and procedures; participate in an investigation of any significant research related accidents or illnesses; and recommend to the Associate Vice-Chancellor for Research appropriate disciplinary action if an investigation reveals significant violations.
6. Perform such other functions as may be delegated to the IBC by the Associate Vice Chancellor for Research.
7. In conjunction with the BSO, responsibilities of the IBC include:
 - a. Approve design specifications and criteria for containment facilities.
 - b. Review and certification of Biosafety Level 3 laboratories.
 - c. Review and final approval of policies and procedures related to select agents, including access, inventory management, laboratory protocols and emergency response plans.
 - d. Review and assessment of compliance with permit-related requirements for work with materials from USDA Animal and Plant Health Inspection Service (APHIS): Veterinary Services (VS), Plant Protection and Quarantine (PPQ), Biotechnology Regulatory Services (BRS); and Environmental Protection Agency (EPA).

The IBC is specifically responsible for the review and approval of research protocols involving the use of biohazardous agents including, but not limited to:

1. Recombinant DNA molecules
2. Infectious agents, including:
 - a. Etiological agents capable of causing disease in healthy (immunocompetent) human adults (i.e. agents classified as Risk Group 2 or higher);
 - b. Etiological agents capable of causing disease in healthy animals, including those that require a USDA APHIS VS permit for import or interstate movement;
 - c. Plant pathogens that are listed as USDA APHIS Select Agents (see Section V, M or Appendix A of this Charter), those that have been quarantined or regionally restricted by PPQ, and/or those that pose a high risk to local flora;
3. Acute toxins of biological origin;
4. Venomous animals manipulated and/or housed in laboratories or other indoor facilities (e.g. greenhouses); and
5. Poisonous plants posing a risk to humans via dermatological contact, inhalation, or other route of exposure.

Research protocols are reviewed by members of the Committee. *However, it is not the responsibility of the IBC to critique a PI's research program. Registrations are reviewed for biological containment and biological safety concerns only.*

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. For more information on the statement on University Employee Protections Against Liability, contact the Office of the Vice-President, General Counsel or you can download the policy at <http://www.lib.utk.edu/~gco/liability.html>.

B. *Biological Safety Officer*

The Biological Safety Officer(s) (BSO) employed by UT is the primary intermediary between PIs and the IBC. The BSO also serves as the Biosafety Program representative for all regulatory and research compliance inspections. The BSO shall:

1. Manage the Biosafety Program and support implementation of IBC policies and procedures.
2. Assist laboratories in conforming to pertinent regulatory guidelines and IBC policies by providing training, facility inspections, and communication of Biosafety Program and related regulatory requirements (i.e., dangerous goods shipping, regulated medical waste, etc.).
3. Perform annual inspections of BSL-2 and BSL-3 laboratories for compliance with *NIH Guidelines*, the CDC “Biosafety in Microbiological and Biomedical Laboratories” guide, and the OSHA Bloodborne Pathogens Standard as applicable.
4. Screen research protocols submitted by PIs and make recommendations to the IBC Chair.
5. Prepare periodic reports for institutional management regarding IBC activities and Biosafety Program status.
6. Screen all protocols submitted to the Institutional Animal Care and Use Committee (IACUC) for identification of occupational hazards; consult with animal facility management, Attending Veterinarians and PIs regarding appropriate containment procedures for biohazardous agents.
7. Ensure preparation of minutes of IBC meetings.

C. *Associate Vice Chancellor for Research*

The Associate Vice Chancellor for Research is responsible for ensuring that research is conducted in full conformity with the provisions of the references as set forth in this document. In order to fulfill this responsibility, the Associate Vice Chancellor for Research shall:

1. Establish and implement policies that provide for the safe conduct of research and teaching involving biohazardous agents.
2. Maintain an active IBC; appoint the IBC Chair, Vice-Chair and committee members as needed.
3. Through the IBC and the BSO, ensure compliance with the regulations and guidelines by PIs conducting research at UT.
4. Direct 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. It is the responsibility of the Deans of each academic unit to provide the necessary resources for implementation of the Biosafety Program in teaching laboratories and exercises.
5. Through the Biosafety Program, provide adequate resources for the dissemination of information on biohazardous agents and biosafety procedures, including training programs and workshops.

6. Provide resources for medical surveillance measures to protect the health and safety of employees.
7. Represent the IBC as needed.

D. Office of Research Compliance and Compliance Officer

The Office of Research Compliance and the Compliance Officer are located in the Office of the Associate Vice Chancellor for Research. The Office of Research Compliance is responsible for the following:

1. Maintain a secure electronic database with all registration documents on research protocols involving biohazardous agents, including recombinant DNA use at UT.
2. Officially archive all records pertaining to the actions and decisions of the IBC.
3. Maintain a paper file for each registration.
4. Monitor Federal, State of Tennessee, and local regulatory trends, and communicate any changes to the BSO and the IBC.
5. Generate annual reports to NIH.
6. Work closely with the Associate Vice Chancellor for Research to coordinate all compliance areas.

E. Department Head

Department heads shall:

1. Review and approve IBC registrations submitted by department faculty members.
2. Ensure that appropriate facilities are available to control biohazardous agents and to enable PIs to comply with pertinent campus policies.
3. Ensure that the PI and all personnel listed on a registration have training that is commensurate with the proposed project.
4. Ensure that the project design and monitoring methods meet all relevant safety standards.
5. Ensure that work errors and conditions that may result in personal injury are corrected.
6. Notify the BSO of new faculty hires, preferably before the new PI arrives on campus, if he/she plans to work with recombinant DNA molecules, agents infectious to humans, animals and plants, acute biological toxins or human-derived materials (see Check List for New Researchers; http://research.utk.edu/forms_docs/checklist.pdf).
7. Notify the BSO/IBC if a PI can no longer carry out his/her responsibilities as outlined in Section IV-F of this Charter (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:
 - a. 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 provisions outlined in Section IV-F of this Charter; or
 - b. 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 provisions outlined in Section IV-F of this Charter; or
 - c. Terminate the registration.

F. 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 responsible for full compliance with the policies, practices and procedures set forth by UT. 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 (laboratory directors or supervisors) or faculty, this does not absolve the PI of his/her ultimate responsibility. The PI remains accountable for all activities occurring in his/her laboratory. 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. *As part of general responsibilities the PI shall:*

1. Develop and implement written laboratory-specific biosafety procedures that are consistent with the nature of current and planned research activities and 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.
2. Delay initiation of research (other than that classified as III-E or III-F under *NIH Guidelines*) until the research protocol has been approved by the IBC.
3. Ensure that all laboratory personnel, maintenance personnel and visitors who may be exposed to any biohazardous agents 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 potential exposure to biohazardous agents be informed of such hazards and appropriate safety practices before entering or working in such hazards.
4. 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.
5. Ensure that research materials are properly decontaminated before disposal and that all employees are familiar with the appropriate methods of waste disposal. For specific decontamination procedures contact the BSO or visit the Biosafety website (<http://biosafety.utk.edu>).
6. Report any significant problems, violations of the policies, practices and procedures to the BSO as soon as reasonably possible.
7. Notify the BSO immediately if:
 - a. A laboratory-acquired infection is known or suspected, or
 - b. A spill of any quantity involving an agent infectious to humans, plants, or animals occurs in a public area.
8. Receive training in standard microbiological techniques.
9. Ensure that all research personnel are appropriately trained in biosafety and receive appropriate medical surveillance when needed. The PI should contact the BSO for assistance with all biosafety training needs.
10. Coordinate with the BSO and develop emergency plans for handling accidental spills and personnel contamination.
11. Create and foster an environment in the laboratory that 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, BSO, Risk Management, or State or Federal agencies.

12. Comply with shipping requirements for biohazardous agents and select agents. The BSO conducts shipping training as required for all lab personnel. 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. These materials are often regulated for shipment and must only be shipped by personnel who have been properly trained and authorized by UT to ship such materials on its behalf.

In submitting proposed work to the IBC, the PI shall:

1. Make an initial determination of the required levels of physical and biological containment in accordance with the requirements set forth by the *NIH Guidelines* and the CDC “Biosafety in Microbiological and Biomedical Laboratories” document as applicable.
2. Select appropriate microbiological practices and laboratory techniques to be used for the research.
3. Complete and submit the appropriate IBC registration form(s). Registration forms for the use of infectious agents, recombinant DNA, and acute biological toxins can be found at: <http://biosafety.utk.edu/forms/>.
4. Submit any significant changes in a given project to the BSO for review and approval. (See Section VI of this Charter)

Prior to initiating research, the PI shall coordinate with the BSO to:

1. Make available to all laboratory staff and involved facilities staff (such as animal care staff) the protocols that describe the potential biohazards and the precautions to be taken.
2. Instruct and train all research personnel in:
 - a. Identification of the biohazard(s) present,
 - b. Practices and techniques required to ensure safety and reduce potential exposure,
 - c. Procedures for dealing with accidents, spills and exposures.
3. Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).
4. Ensure that collaborators are made aware in advance of any biohazardous agents sent to them, and comply with all applicable packaging and shipping requirements. These materials are often regulated for shipment and must only be shipped by personnel who have received proper training and are authorized by UT to ship such materials on its behalf.
5. Maintain a formal inventory of all biological material received and sent. Logs should include the approximate quantity of the materials and where it is stored in the laboratory.

During the conduct of the research the PI shall:

1. Supervise the safety performance of the laboratory staff to ensure that required safety practices are employed.
2. Investigate and report in writing to the IBC any significant problems pertaining to the operation and implementation of containment practices and procedures.
3. Immediately notify the BSO of any laboratory spills, accidents, containment failure or violations of biosafety practice which result in the release of biohazardous agents and/or

the exposure of laboratory personnel (or the public) to infectious agents. The IBC may be consulted by the BSO if necessary.

4. Correct work errors and conditions that may result in the release of biohazardous agents.
5. Ensure the integrity of all containment systems used in the project.
6. Restrict access as required by the laboratory-specific biosafety practices and procedures, and by the biosafety containment level approved by the IBC.
7. Immediately notify the BSO if a Select Agent (see Section V, M; Appendix A of this Charter) or other high-consequence pathogen (i.e. Risk Group 3 or 4) has been isolated and confirmed from environmental and/or diagnostic specimens.

V. IBC POLICIES AND PROCEDURES

A. IBC Membership

Membership of the IBC will include scientists, clinical investigators and administrators from UT, and community representatives. Based on *NIH Guidelines* (section IV-B-2-a), the minimum number of IBC members is five. Members are appointed by the Associate Vice-Chancellor for Research for a renewable term of two years. New committee members are usually 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 a mix of technical expertise (e.g. recombinant DNA; agents infectious to humans, animals or plants; acute toxins of biological origin) representative of the research protocols being reviewed, and to represent the diversity of the University community. Committee composition will be maintained in accordance with *NIH Guidelines*.

Special membership requirements:

1. *Community representation: NIH Guidelines* stipulate that at least two members of the IBC not be affiliated (non-affiliated members) with the institution (UT), but be representative of the interests of the local general population. Community members may include officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community. While the *NIH Guidelines* do not stipulate a particular educational background for a non-affiliated member, this person(s) must be able to understand the basic concepts of the registration(s) submitted to the committee.

The Non-affiliated Member has the following responsibilities:

- a. Attend all the IBC meetings;
- b. Be up to date on relevant biosafety protocols administered by the University of Tennessee;
- c. Represent the interests of the surrounding community with respect to the environment and public health;
- d. Review all registrations submitted to the committee;

- e. Proofread the non-technical summary for general understanding by a layperson;
- f. Must not have an affiliation (financial or otherwise) with the University; and
- g. Must have a conflict-of-interest statement on file with the Office of Research Compliance.

The IBC and the Office of Research Compliance should be able to justify its selection of non-affiliated IBC members should the independence and qualifications of those individuals ever be called into question.

- 2. *Ex-officio Non-voting members:* By virtue of their administrative or regulatory positions, the BSO, the Associate Vice-Chancellor for Research, the UTK Compliance Officer, and any designated UT compliance personnel are all *ex-officio* non-voting members of the IBC. The BSO will become a voting member if UT engages in recombinant DNA molecule activities requiring BSL-3 containment or any large-scale (>10 liters) recombinant DNA molecule activities.
- 3. *Subject Matter Expertise:* If a registration is outside the area of 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 UT System if necessary.

B. IBC Member Training

All new members are required to complete training on the regulatory responsibilities and functions of the IBC. This training must be completed before participation in voting activities of the committee. Training will be administered by the IBC Chair or his/her designee. All IBC members must also complete annual retraining, covering topics that will enhance the committee's understanding of Biosafety-related issues and institutional research review policies. The annual retraining will be administered by the IBC Chair or his/her designee.

C. Member Responsibilities

The IBC Chair shall:

- 1. Conduct meetings.
- 2. Approve registrations.
- 3. Review and approve amendments and updates as necessary (see Section VI, B of this Charter).
- 4. Ensure member training; this task may be designated to another qualified individual.
- 5. Prescreen submitted registrations.
- 6. Set meeting agendas and establish meeting dates.
- 7. Maintain the IBC website.

The Vice-Chair shall:

- 1. Substitute for the Chair as necessary.
- 2. Annually review the IBC Charter and update as needed.
- 3. Prescreen submitted registrations.

4. Approve registrations in the absence of the Chair.

The IBC members shall:

1. Be current on biosafety training.
2. Attend monthly meetings; notify the IBC Chair if attendance is not possible.
3. Review all registrations and provide feedback to the Chair or Vice-Chair if he/she cannot attend meetings.
4. Complete biosafety regulatory awareness training (IBC training) before participating in voting activities of the committee.
5. Complete annual retraining covering IBC-related topics (Section V, B of this Charter).

D. IBC Schedule and Meetings

Currently, IBC meetings are scheduled for the third Wednesday of each month unless otherwise indicated. Usually, meetings are open to the public and are announced at an open web site (www.tennessee.edu/ibc). All meeting materials will be posted to the IBC website no later than 7 days before the regularly scheduled meeting. However, the IBC, in its discretion, may close the meeting, or part of a meeting, and not post all meeting materials on the website 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.

1. *Agenda.* The agenda will be prepared according to Robert's Rules of Order. Agendas will be made available to the public upon request.
2. *Minutes.* Minutes from each IBC meeting will be kept per guidance issued by the NIH Office of Biotechnology Activities (OBA). Drafted minutes are posted to a secure website accessible by IBC members and designated non-voting members pending IBC approval. Once approved, minutes will be made available to the public via the IBC website.
3. *Supplementary Material.* Registrations submitted to the IBC are posted to a secure website accessible by IBC members and designated non-voting members.
4. *Registration Deadline Date.* All registrations for the IBC meeting must be forwarded to the BSO no later than 14 days before the IBC meeting and posted to the IBC website at least 7 days before the meeting.

E. Quorum

A quorum is defined as 50 percent plus one of the voting members and must include at least one community representative. Non-voting members are not counted when determining a quorum. Written proxies do not count toward a quorum.

F. Proceedings

Meetings will be conducted in accordance with Robert's Rules of Order. The Chair will issue all points of order, summarize registrations as necessary, moderate discussion, and call for motions. Motions, seconds, and/or other propositions may be made by any voting member of the IBC. Motions pass by a simple majority of the voting members present.

G. Charter Acceptance and Modification

Acceptance of the Charter and any future modifications must be approved by the voting members of the IBC and the UT Administration. A two-thirds ($\frac{2}{3}$) majority of the voting membership of the IBC is required to accept any revisions to this document. This vote may be submitted by a written proxy if necessary.

H. Conflict Of Interest

A conflict of interest is loosely 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 FI0125). Any IBC member with financial or other interests with 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 community representatives, must have a conflict of interest statement on file with the University. Committee members may participate in discussion, but must abstain from voting on registrations associated with the conflict of interest.

I. Clinical Trials

All human clinical trials involving recombinant DNA molecules will be referred to the IBC at The University of Tennessee Health Science Center in Memphis which has the expertise and experience to adequately review these registrations.

J. Bloodborne Pathogens.

All studies involving human-derived materials including unfixed tissues, primary cells and established cell lines must be regarded as potentially biohazardous and are regulated under the OSHA Bloodborne Pathogens (BBP) Standard (<http://www.osha.gov/SLTC/bloodbornepathogens/standards.html>). These materials must be manipulated under BSL-2 containment conditions and are regarded as "potentially infectious materials" under the BBP Standard. The BSO serves as the Bloodborne Pathogens Exposure Control Program Administrator for laboratory research use of human-derived materials. Laboratories using these materials do not need to register with the IBC but must document their use of human-derived materials with the BSO. The current BBP Exposure Control Plan for Research Personnel is available at <http://biosafety.utk.edu>.

K. Transgenic Plants

Transgenic plants created and maintained in the laboratory and greenhouse environment are subject to provisions of *NIH Guidelines* and are part of the IBC purview. Field releases, however, are not covered by *NIH Guidelines* because the release of those organisms is subject to notification and permit requirements under the USDA. To effectively manage releases in accordance with the provisions of USDA notification or permit, all UT personnel and units associated with the work must be informed of these provisions and restrictions, even if the UT PI is not the responsible person on the notification or permit. Failure to do so may result in

accidental environmental release which can lead to sanctions for UT and the holder of the notification or permit. To enhance communication between PIs and land management personnel, and to establish a mechanism to monitor field release activities, the IBC developed a supplemental document entitled, “Addendum: Field Release of Materials Requiring a USDA APHIS PPQ/BRS Permit or Notification,” which must be submitted with work plans for AgResearch Projects. A copy of these registration documents will be forwarded to the IBC Chair for review and record keeping.

L. *Transgenic Animals*

The purchase or transfer of transgenic rodents for experiments that require only BSL-1 containment are exempt from *NIH Guidelines*. The creation of transgenic rodents and other animals, however, is not exempt and must be registered with and approved by the IBC. The creation of transgenic animals includes direct gene delivery (i.e. transformation) and/or the crossing of two different transgenic strains (or a transgenic strain crossed with a non-progenitor wild-type strain).

M. *Select Agents and Toxins*

Infectious agents and toxins that are considered by the Department of Health & Human Services (DHHS) or USDA to have the potential to pose substantial harm or a severe threat to human, animal or plant health, or plant products are regulated as ‘select agents’. The current select agent list (see Appendix A of this Charter) and details of the registration/approval process with the appropriate regulatory agency is available on the Biosafety Program website (<http://biosafety.utk.edu>). This process includes a security clearance component, conducted by the Federal Bureau of Investigation, for all who will have access to the select agent or toxin. If a PI possesses, plans to acquire, or conduct research with select agents, then they must contact the BSO immediately.

For select agent listed toxins, PIs may possess an amount up to the ‘per Principal Investigator’ quantity listed for the toxin without pursuing registration as a ‘select agent’ laboratory. To ensure that toxin quantities are accurately documented and materials are handled in a safe and secure manner, the IBC and Biosafety Program require registration of the toxin use with the IBC. The form for registering the use of select-agent toxins or an acute toxin of biological origin is available through the BSO. Handling and storage procedures will require input and surveillance activities (periodic inspections) by both the BSO and a Chemical Safety Subject Matter Expert for the campus where the toxins are to be used and stored.

Any PI conducting research with a select agent must ensure that adequate security is available to prevent unauthorized access to facilities. The CDC and NIH have made several requirements or recommendations for enhancing the security of laboratories working with select agents. For further information of select agent lab security, visit the National Select Agents Registry website (<http://www.selectagents.gov/SecurityRelatedInformation.html>).

N. *Export Control*

Work with controlled chemicals, biological agents, and toxins may be subject to Federal regulations regarding the export of these materials, or technology or knowledge related to their use. An export is defined not only as a physical transfer/disclosure of an item outside the U.S., but also as a transfer/disclosure in any form of a controlled item or information within the U.S. to anyone who is a foreign national (not a U.S. citizen or permanent resident). More information on export control laws, exclusions and exemptions, and licensing requirement is available from the UTK Office of Research (<http://research.utk.edu/exportcontrol/>).

Dual use research encompasses biological research with legitimate scientific purpose, the results of which may be misused to pose a biologic threat to public health and/or national security. At this time, review of dual use research is not within the purview of the IBC. However, the National Science Advisory Board for Biosecurity (NSABB; <http://www.biosecurityboard.gov/>) is currently developing policy related to dual use research. Export control issues are reviewed by the Office of Research.

VI. PROTOCOL APPROVAL PROCEDURE

The use of standard registration forms makes it easier for IBC members to review projects and to make recommendations as to proper safety procedures. There are 4 forms that cover most biological research conducted at UT:

1. Laboratory Research Use of Infectious Agents Registration Form
2. Registration for Use of Recombinant DNA Molecules
3. Registration for Use of Acute Biological Toxins
4. Human Derived Materials Registration Form (note: this form is to be used when registering human derived materials only)

Investigators can access these forms from UT's Biosafety website (<http://biosafety.utk.edu/forms>) or the IBC website (www.tennessee.edu/ibc).

A. *Registration Approval Procedures*

After a registration is submitted, the BSO will decide whether more information is necessary and, if so, will contact the PI. Once the registration is complete, the BSO communicates with the IBC Chair summarizing the salient characteristics of the study and listing any IBC precedents. The following procedures are followed:

1. *Committee Approval.* Registrations are posted to a secure website accessible to all IBC members one week prior to the scheduled meeting. Each member is expected to review all registrations prior to the meeting. However, the IBC Chair may request a designated member review based on high registration volume and/or subject matter expertise. In the event of a designated member review, the assigned reviewer(s) will summarize the registration(s) and present comments and recommendations. The IBC will decide on all registrations by a formal vote. When quorum is established, a simple majority of the voting members present is required to accept or reject an registration.

2. *Investigator Presentations.* When the Chair deems it advisable, investigators will be invited to IBC meetings to clarify their registration and respond to members' questions.
3. *Communicating with IBC.* Investigators communicate with the IBC through the BSO or through the IBC Chair. Registrations and other formal communications with the IBC must be signed by the PI.
4. *Protocol Termination.* Approval may be canceled if the PI is found to be routinely in violation of IBC policies and regulations. Recombinant DNA and infectious agent research not complying with NIH guidelines may cause NIH action affecting individual and institutional funding.

B. Updates and Amendments to Approved Registrations

Any changes to approved registrations should be submitted to the BSO in writing. The BSO will determine if the change requires IBC approval. Changes are processed the same way as original submissions, without the necessity of submitting a formal registration. There are three types of changes:

1. *Updates* are changes without safety consequences. For instance, staff changes or addition of new strains of previously approved or closely related cell type are updates. Updates should be sent to the BSO.
2. *Amendments* are necessary when the change may have safety consequences but the basic thrust of the study stays the same. In general the change will not involve a change in containment. For example, addition of a new pathogen or vector to a study will usually require an amendment. Addition of a toxic gene will also require an amendment. Amendment requests will be approved by the IBC Chair. The BSO will notify the Chair explaining the change and provide a recommendation for how to proceed and a notification letter to the PI.
3. *New Registrations* are required when there is a change in the basic thrust of a project; i.e., a new goal.

C. Annual Reports for Registered Laboratory Activities

Registration documents approved by the IBC are valid for three (3) years. In order to remain valid during that period, annual reports will be completed to ensure that lab activities are consistent with the approved registration.

1. *Recombinant DNA Molecule use.* The BSO will send the PI an annual report document approximately one (1) month before the anniversary date of the original approval. The PI must complete this document and return it within 30 days of the specified due date.
 - a. If there is no response from the PI, a reminder will be sent and a 30 day grace period will be granted. If there is no response from the PI at the end of the grace period, the registration will be terminated and the PI will be required to submit a new registration. The IBC Chair and the PI's Department Head and Dean will be notified of the termination.
 - b. Upon receipt of an annual report from the PI, the BSO, in conjunction with the IBC Chair, will review the report to determine if changes in laboratory activities may impact the review category or the BSL assignment of the work. If the

changes will impact either of these criteria, the IBC Chair will add the registration to the next month's agenda for reconsideration by the IBC.

2. *Infectious Agent Registration (or recombinant DNA molecule use requiring BSL-2 facilities and containment practices)*. The BSO will complete a lab inspection and consult with the PI to verify compliance with applicable biosafety containment practices in order to document any changes in the work. If changes are significant (i.e. agents under study are unrelated to those documented in the current registration, procedures are planned that have an elevated risk, etc.), the BSO will request that the PI capture these changes in the annual report or amendment. This annual report/amendment will be submitted to the IBC Chair for reconsideration by the IBC. The same annual reporting schedule indicated in (1) above will apply.

D. *Failure to Comply*

PIs are expected to comply with the IBC standards outlined in this Charter. Noncompliance includes, but is not necessarily limited to:

1. Failure to register biohazardous agents, including non-exempt recombinant DNA molecules;
2. Failure to provide annual updates and/or other required documentation within 60 days of the specified due date (see Section VI-C-1 of this Charter for details);
3. Poor biological safety/biological containment practices as documented through routine lab inspections; or
4. Failure to correct a documented (confirmed) biological safety complaint or concern.

Noncompliance will be reported to the IBC which may result in suspension or termination of all approved registrations. The PI's Department Head, Dean, and/or other applicable administrators will be notified of the noncompliance, while granting agencies or regulatory authorities may be notified as required by their respective reporting standards.

Appendix A. HHS/USDA SELECT AGENTS LIST (Effective November 17th, 2008)

HHS NON-OVERLAP SELECT AGENTS & TOXINS	
<p>Botulinum neurotoxin producing species of <i>Clostridium</i> Cercopithecine herpesvirus 1 (Herpes B virus) <i>Coccidioides immitis/Coccidioides posadasii</i> <i>Coxiella burnetii</i> Crimean-Congo haemorrhagic fever virus Eastern equine encephalitis virus Ebola viruses <i>Francisella tularensis</i> Lassa fever virus Marburg virus Monkeypox virus Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments <i>Rickettsia prowazekii</i> <i>Rickettsia rickettsii</i> South American haemorrhagic fever viruses (Flexal, Guanarito, Junin, Machupo, Sabia,)</p>	<p>Tick-borne encephalitis complex (flavi) viruses (Central European tick-borne encephalitis, Far Eastern tick-borne encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, Russian spring and summer encephalitis) Variola major virus (Smallpox virus) Variola minor virus (Alastrim) <i>Yersinia pestis</i></p> <p style="color: blue;">Toxins: (Amounts Permissible Per Principal Investigator) Abrin (100 mg) Botulinum neurotoxins (0.5 mg) <i>Clostridium perfringens</i> epsilon toxin (100 mg) Conotoxins (100 mg) Diacetoxyscirpenol (1000 mg) Ricin (100 mg) Saxitoxin (100 mg) Shiga-like ribosome-inactivating proteins (100 mg) Shigatoxin (100 mg) Staphylococcal enterotoxins (5.0 mg) T-2 toxin (1000 mg) Tetrodotoxin (100 mg)</p>
HHS/USDA OVERLAP SELECT AGENTS & TOXINS	
<p><i>Bacillus anthracis</i> <i>Brucella abortus</i> <i>Brucella melitensis</i> <i>Brucella suis</i> <i>Burkholderia mallei</i> (formerly <i>Pseudomonas mallei</i>) <i>Burkholderia pseudomallei</i> (formerly <i>Pseudomonas pseudomallei</i>)</p>	<p>Hendra virus Nipah virus Rift Valley fever virus Venezuelan equine encephalitis virus</p>
USDA SELECT AGENTS & TOXINS	
<p>African horse sickness virus African swine fever virus Akabane virus Avian influenza virus (highly pathogenic) Blue tongue virus (exotic) Bovine spongiform encephalopathy agent Camel pox virus Classical swine fever virus <i>Cowdria ruminantium</i> (Heartwater) Foot and mouth disease virus Goat pox virus Japanese encephalitis virus</p>	<p>Lumpy skin disease virus Malignant catarrhal fever virus (exotic) Menangle virus <i>Mycoplasma capricolum</i> subsp. <i>capripneumoniae</i> <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> Peste Des Petits Ruminants virus Rinderpest virus Sheep pox virus Swine vesicular disease virus Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3 Virulent Newcastle disease virus (velogenic)</p>
LISTED PLANT PATHOGENS	
<p><i>Peronosclerospora philippinensis</i> (<i>P. sacchari</i>) <i>Phoma glycinicola</i> (formerly <i>Pyrenochaeta glycines</i>) <i>Ralstonia solanacearum</i> race 3, biovar 2 <i>Rathayibacter toxicus</i></p>	<p><i>Schlerophthora rayssiae</i> var <i>zeae</i> <i>Synchytrium endobioticum</i> <i>Xanthomonas oryzae</i> <i>Xylella fastidiosa</i> (citrus variegated chlorosis strain)</p>
<p style="color: blue;"><i>Note: Toxins are the only select agent-listed materials with de minimis quantity exemptions. Even so, there are restrictions on purchasing, distributing and transporting these toxins. Contact Brian Ranger, Biosafety Officer at 974-1938 if you plan to purchase, use, store, or transport a listed toxin.</i></p>	

APPENDIX B.
CERTIFICATION REQUIREMENTS FOR BL3 LABORATORIES
Guidelines for the IBC Commissioning Committee

1. A committee of 4 or 5 members:
 - a. All the members do not have to be IBC members, but should all have a connection with a University of Tennessee affiliated institution.
2. The membership should be:
 - a. An IBC public member;
 - b. A veterinarian for BL3-N facilities;
 - c. Two IBC voting members without conflict for the site or people involved in the BL3 facility;
 - d. A Biosafety Officer other than the one responsible for the inspected institution.
3. Before the inspection:
 - a. The Commissioning Committee will meet once, perhaps with a PI presentation, to plan the visit and to discuss the issues involved.
 - b. They will select a Chair that will be responsible for leading meetings and preparing the final report.
 - c. The Commissioning Committee will be provided:
 - i. As built engineering plans
 - ii. SOPs as requested, such as:
 1. Entry and exit procedures
 2. Emergency Plans
 3. Training Plans
4. The inspection:
 - a. The Commissioning Committee gathers at the site. They will be provided with a meeting room to privately discuss the upcoming inspection, any last minute details, and to go over the planned visit.
 - b. The Commissioning Committee will gather in the same room after the inspection to formulate questions that arose during the visit and to prepare for the final report. The Chair will outline the final report and give each member responsibility for writing a short report on one specific aspect of the inspection.
5. After the inspection:
 - a. The Commissioning Committee members will submit their short reports to the Chair via e-mail.
 - b. The Chair will put these sections into a final report and distribute the report to the Commissioning Committee for final comments.
 - c. The Chair will manage an e-mail vote on whether to approve the facility, to approve with stipulations, to reject, or to defer approval.
 - d. The final report will be sent to the IBC Chair for distribution before the next IBC meeting.
6. At IBC meeting:
 - a. If an IBC member is associated with the BL3 facility this will be considered a conflict of interest and they will be asked to leave the room while the proposal is being discussed.
 - b. The Commissioning Committee Chair will present and summarize the final report. A recommendation as to approval will be made to IBC.
 - c. Individual Commissioning Committee members will present their point of view.
 - d. IBC will vote on whether to approve, approve with stipulations, reject or defer the BL3 facility.

APPENDIX C: Abbreviations and Important Links

Abbreviations	Definition	Website
APHIS	Animal and Plant Health Inspection Service (Part of the US Agriculture Department)	http://www.aphis.usda.gov
BSL1, BSL2, BSL3	Biosafety Level 1, Biosafety Level 2, Biosafety Level 3	
BSO	Biosafety Officer	http://biosafety.utk.edu
CDC	Centers for Disease Control and Prevention	http://www.cdc.gov/
	Export Control	http://research.utk.edu/exportcontrol/
IACUC	Institutional Animal Care and Use Committee	http://iacuc.tennessee.edu/
IBC	Institutional Biosafety Committee	http://www.tennessee.edu/ibc
IRB	Institutional Review Board Human Subjects	http://research.utk.edu/humansubjects/
NIH	National Institutes of Health	http://www.nih.gov
	NIH Guidelines for Research Involving Recombinant DNA Molecules	http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm
NSABB	National Science Advisory Board for Biosecurity	http://www.biosecurityboard.gov/
OBA	Office of Biotechnology Activities	http://www4.od.nih.gov/oba/
OSHA	Occupational Safety and Health Administration	http://www.osha.gov/
	OSHA Bloodborne Pathogens Standard	http://www.osha.gov/SLTC/bloodbornepathogens/index.html
RAC	Recombinant DNA Advisory Committee	http://oba.od.nih.gov/rdna_rac/rac_about.html
TOSHA	Tennessee Occupational Safety and Health Administration	http://tennessee.gov/labor-wfd/tosha.html
	Select Agents List	http://www.selectagents.gov/index.html
	UT Biosafety Office	http://Biosafety.utk.edu