Policy: **BSP-G 01v15**	Revised: **November 1, 2015**
Name: **Use of Biohazards in Research, Teaching & Diagnostic Testing**	Approved: **November 1, 2015**
Areas Affected: **All UTK-area programs handling biological hazards**	Next Review: **November, 2016**

I. PURPOSE, APPLICABILITY & SCOPE

The University of Tennessee, Knoxville-area campuses, including: Knoxville, the Institute of Agriculture; College of Veterinary Medicine; and Graduate School of Medicine (UTK-A hereafter); are committed to protecting faculty, staff, students, visitors, the general public and the environment from exposures (or potential exposures) to biological hazards, and to ensuring that all activities involving biological hazards and the facilities used to conduct such work are in compliance with applicable U.S. Federal, State and local laws, regulations and guidelines (see Section IV below):

This policy applies to research, teaching, diagnostic testing and other activities conducted at, sponsored by, or on behalf of UTK-A, and involving:

- Recombinant DNA molecules or synthetic nucleic acids as defined in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (hereafter *NIH Guidelines*), including transgenic plants and animals;
- Biological agents (bacteria, viruses, fungi, protozoa, parasites, and prions) which may cause disease in humans, animals or plants and require containment and safeguards at Biosafety Level-2 (BSL-2) or higher (note: biological agents deemed low-risk or those not known to cause disease in humans, animals or plants are exempt from this policy per documented risk assessment);
- Acute biological toxins having an LD_{50} < 100 ng/kg in mammals and/or those defined as Select Agent Toxins;
- Human or nonhuman primate blood, blood products, tissues, secretions, excretions, or cell lines unless documented to be free of bloodborne pathogens or otherwise deemed low risk per documented risk assessment;
- Venomous animals manipulated and/or housed in laboratories or other indoor facilities;
- Poisonous plants posing a risk to humans via dermatological contact, inhalation, or other route of exposure;
- Novel nanoparticles conjugated to biologically active or cell-modifying molecules;
- Diagnostic specimens or environmental samples deemed likely to contain any of the above and posing a significant risk to humans, animals, plants or the environment per documented risk assessment.

II. ABBREVIATIONS, ACRONYMS & DEFINITIONS

A. *Abbreviations & Acronyms*

1. APHIS – Animal & Plant Health Inspection Service
2. BMBL – Biosafety in Microbiological & Biomedical Laboratories (5th ed.)
3. BSL – Biological Safety (or Biosafety) Level
4. BSO – Biological Safety Officer
5. CDC – Centers for Disease Control and Prevention
6. CFR – Code of Federal Regulations
7. DHHS – United States Department of Health & Human Services
8. DNA – Deoxyribonucleic Acid
9. DOT – Department of Transportation
10. EPA – Environmental Protection Agency
11. FDA – Food & Drug Administration
12. IACUC – Institutional Animal Care and Use Committee
13. IBC – Institutional Biosafety Committee
14. ICAO – International Civil Aviation Organization
15. DO – Designated Official
16. LD_{50} – Median Lethal Dose
17. NIH – National Institutes of Health
18. OSHA – Occupational Safety and Health Administration
19. PPE – Personal Protective Equipment
20. PI – Principal Investigator
21. rDNA – Recombinant DNA
22. RO – Responsible Official (Select Agent Program)
23. TCA – Tennessee Code Annotated
24. TDEC – Tennessee Department of Environment & Conservation
25. USDA – United States Department of Agriculture
26. UTK – University of Tennesse, Knoxville
27. UTK-A – University of Tennessee, Knoxville-Area Campuses (Knoxville, the Institute of Agriculture, College of Veterinary Medicine, & Graduate School of Medicine)

B. ***Definitions***

1. **Biological hazard (biohazard)** – any material of biological origin that may pose an infectious disease risk or otherwise negatively impact the health of humans, animals, plants or the environment. Examples include but are not necessarily limited to: infectious agents (bacteria, viruses, fungi, etc.), recombinant DNA molecules, biological toxins, diagnostic specimens (blood, tissue, cells, and secretions), venomous animals, poisonous plants, etc.
2. **Biological Safety Officer** – the individual assigned to implement the policies of the IBC and ensure that research, teaching, and diagnostic testing are in accordance with applicable regulations, standards, and guidelines.
3. **Designated Official** – the individual appointed to oversee the University's Biosafety Program. The UTK Assistant Vice-Chancellor for Research, Responsible Conduct of Research, and Research Integrity Officer is the Designated Official for the UTK-A Biosafety Program.
4. **Dual use research of concern –** life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, matériel, or national security.
5. **Institutional Biosafety Committee** – appointed committee of UTK-A faculty, technical staff, and community representatives which establishes, recommends, and/or approves policies on the proper use of biological hazards. The IBC also recommends disciplinary actions in the event of noncompliance with applicable standards and guidelines and/or the unsafe use, storage, or security of biological hazards.
6. **Laboratory Coordinator** – the individual with primary responsibility for the use of biological agents in the University's teaching or diagnostic testing laboratories.
7. **Principal Investigator –** the faculty member or other University employee in whose assigned space a research activity is conducted. The Principal Investigator is responsible for compliance with all institutional policies and procedures and the safety of all visitors, students, staff and other faculty working in his/her designated laboratories.
8. **Recombinant DNA and Synthetic Nucleic Acid Molecules** – in the context of the *NIH Guidelines*, recombinant and synthetic DNA molecules are defined as:
    a. molecules that (a) are constructed by joining nucleic acid molecules and (b) can replicate in a living cell, i.e., recombinant nucleic acids;
    b. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; or
    c. molecules that result from the replication of those described above.

9. **Responsible Official –** University appointed official with the legal authority and responsibility to oversee the possession, use and transfer of Select Agents. The RO is appointed by DO, must pass a security risk assessment conducted by the Federal Bureau of Investigation and Criminal Justice Information Services, and be approved by the Federal Select Agent Program.
10. **Select Agents –** infectious agents and biological toxins which have been declared by the DHHS or by the USDA to have the potential to pose a severe threat to public health and safety.

III. ROLES & RESPONSIBILITIES

A. *Designated Official*

The UTK Assistant Vice-Chancellor for Research, Responsible Conduct of Research, and Research Integrity Officer is the DO for the UTK-A Biosafety Program. 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:

1. Establish and implement policies that provide for the safe conduct of research, teaching and diagnostic testing involving biological hazards.
2. Maintain an active IBC; appoint the IBC Chair, Vice-Chair and committee members in accordance with the *NIH Guidelines* and other University requirements as applicable.
3. Grant the IBC and BSO authority to oversee the safe and responsible use of biological hazards at the UTK-A campuses.
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.
5. Provide adequate resources for the dissemination of information on biosafety policies and procedures, including training programs and workshops.
6. Coordinate or provide resources for medical surveillance measures or occupational health programs to protect the health and safety of faculty, staff, students, and visitors.
7. Impose or uphold disciplinary actions or sanctions on principal investigators or laboratory coordinators who fail to comply with established regulations, standards, guidelines, or University policies.
8. Report any significant problems, or violations to U.S. Federal, State or local agencies (e.g. NIH, CDC, USDA, etc.) as applicable. If appropriate, agency reporting may be delegated to the IBC or BSO.
9. Represent the IBC as needed.

B. ***Institutional Biosafety Committee***

The IBC establishes, recommends, and approves policies ensuring the prudent management of biological hazards. Policy objectives are to protect faculty, staff, students, research subjects, the general public, and the environment from biological hazards used in University research, teaching, diagnostic testing, or other specified activities. The IBC shall:

1. Establish and monitor policy, practices and procedures for research with biological hazards. Similar policies/procedures for teaching and diagnostic testing may be covered by the IBC or managed administratively by the BSO at the discretion of the committee.
2. Ensure that adopted policies, practices and procedures for work with biological hazards meet applicable regulatory standards and guidelines.
3. Regularly review research involving biological hazards conducted at or sponsored by UTK-A campuses 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 affiliated personnel. The IBC shall ensure that the PI is provided with the results of the review and determination of approval in a timely manner. Similar reviews of teaching and diagnostic testing may be covered by the IBC or managed administratively by the BSO at the discretion of the committee.
4. Assess containment facilities and practices and ensure they are appropriate for the proposed biological hazards and affiliated procedures. 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 significant violation of policies, practices and procedures reported by the BSO; participate in an investigation of any significant research-, teaching-, or diagnostic testing-related accidents or illnesses; suspend or terminate approval for use of biological hazards if such use poses a risk to personnel, public health and safety, or for issues of noncompliance; and set the appropriate corrective action if an investigation reveals significant violations.
6. In conjunction with the BSO and/or RO:
    a. Review and approve design specifications and certification criteria for high-containment laboratories (i.e. BSL-3).
    b. Review and approve policies and procedures related to Select Agents (or others categorized as Risk Group 3), including access, inventory management, laboratory protocols and emergency response plans.
    c. Review and assess compliance with permit or license-related requirements for biological materials subject to USDA APHIS, FDA, and/or EPA regulations.
7. Establish a framework for the identification, management and reporting of dual use research of concern as defined in the *United States Government Policy for*

Institutional Oversight of Life Sciences Dual Use Research of Concern as applicable. In the event that dual use research of concern is identified, the IBC or IBC-selected panel will serve as the Institutional Review Entity (IRE) as described in the policy.

8. Perform other functions as delegated by the DO.

C. ***Biological Safety Officer***

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

1. Manage the administrative tasks of the Biosafety Program and support implementation of IBC policies and procedures.
2. At the discretion of the IBC, establish/implement a framework for oversight of biological hazards and associated procedures in teaching and diagnostic testing labs.
3. Perform risk assessments and provide technical advice to the IBC, DO, and/or RO as required or requested.
4. 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*, the BMBL, the OSHA Bloodborne Pathogens Standard, and/or other standards as applicable.
5. Report any significant problems, violations, or research, teaching, or diagnostic testing-related accidents or illnesses to the IBC, the DO, the RO, or other campus administrators as applicable.
6. Assist PIs, laboratory coordinators, 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).
7. Develop emergency plans for handling accidental spills and personnel contamination and investigate laboratory accidents involving biological hazards.
8. 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.
9. Administratively review proposals and protocols submitted by PIs and laboratory coordinators and make recommendations to the IBC Chair.
10. Screen all 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).

11. Prepare periodic reports for institutional management regarding IBC activities and Biosafety Program status.
12. 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 per requirements of the *NIH Guidelines*.

D. *Responsible Official*

The Responsible Official 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 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:

1. 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.
2. 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.
3. Conduct annual emergency preparedness, spill response, and/or security drills as required.
4. 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.
5. Be granted sufficient authority to speak and act on behalf of the University.

E. ***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 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:

1. Comply with all regulations, standards, guidelines and University policies involving handling, storage, disposal, inventory, security/access, and transportation of biological hazards.
2. 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.
3. Delay initiation of research involving biological hazards until the research protocol has been reviewed and approved by the IBC or BSO as required.
4. Maintain an inventory of all biohazards used or stored in the laboratory. Logs should include the approximate quantity of the materials and where it is stored in the laboratory.
5. Restrict access to the laboratory and stored biological hazards to authorized personnel only.
6. 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.
7. 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.
8. Provide and maintain all 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.
9. 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.
10. 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.
11. 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.

12. Coordinate with the BSO and develop emergency plans for accidental spills and exposures.
13. 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.
14. 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, DO, Risk Management, or State or Federal agencies.
15. Immediately notify the BSO of any laboratory spills, accidents, containment failure or violations of biosafety practice which 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.
16. 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.
17. 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.
18. 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.

F. ***Laboratory Coordinator***

The laboratory coordinator 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 coordinator shall:

1. Comply with all regulations, standards, guidelines and University policies involving handling, storage, disposal, inventory, security/access, and transportation of biological hazards.
2. Register biological hazards with the IBC or BSO (as designated).

3. Complete training, and ensure that all teaching or 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 coordinator.
4. As necessary, communicate to teaching staff and students/trainees the signs and symptoms which may result from accidental exposures to the biological hazards in use.
5. Stipulate the safety precautions to be followed by teaching 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.
6. Determine the proper PPE to be worn for designated procedures. The laboratory coordinator (or designate) shall ensure that PPE is worn as directed and cleaned/replaced as appropriate.
7. 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 if necessary.
8. 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.

IV. GUIDELINES, STANDARDS & REGULATORY REFERENCES

The following regulations, standards, guidelines and policies apply to the possession, use and transfer of biological hazards. In the case of conflict between requirements of the regulatory agencies, the more protective regulations shall prevail, as appropriate.

A. The *NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules* (November, 2013):
http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.pdf
http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html

B. The Centers for Disease Control and Prevention/National Institutes of Health (CDC/NIH) *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (2009):
http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf
http://www.cdc.gov/biosafety/publications/bmbl5/

C. Safety standards promulgated through the (Tennessee) Occupational Health & Safety Administration (OSHA; 29 CFR 1910 et al.):
https://www.osha.gov/law-regs.html
http://www.state.tn.us/labor-wfd/tosha.html

D. USDA Animal & Plant Health Inspection Services (APHIS) pertaining to biological agents, vectors, pests, and/or recombinant molecules affecting animals (9 CFR, Parts 1-199) and plants (7 CFR, Parts 300-381):
http://www.aphis.usda.gov/wps/portal/aphis/home/

E. U.S. DOT regulations applicable to domestic shipments of biological hazards in commerce (49 CFR, Parts 171-180):
http://phmsa.dot.gov/regulations

F. ICAO Technical Instructions applicable to domestic and international shipments of biological hazards by air:
http://www.icao.int/safety/DangerousGoods/Pages/technical-instructions.aspx

G. TDEC Rule 0400-11-01-.04(2)(k)4 covering the packaging and disposal requirements for regulated medical waste:
http://www.tennessee.gov/environment/
http://www.tn.gov/sos/rules/0400/0400-11/0400-11-01.20120917.pdf

H. DHHS/USDA regulations controlling the use of Select Agents & Toxins (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121):
http://www.selectagents.gov/
http://www.selectagents.gov/Regulations.html

I. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (September, 2014):
http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

J. UT System Policy SA0450: Biological Safety:
http://policy.tennessee.edu/safety_policy/sa0450/