THE UNIVERSITY OF TENNESSEE

System-wide Policy: SA0450 - Biological Safety	
Version: 3	**Effective Date: 02/09/2021**

SA0450 – Biological Safety and Select Agents

Scope:

This policy applies to each University of Tennessee campus, college, or institute utilizing hazardous biological materials and/or select agents.

Purpose:

To establish requirements for a written program for the safe use, storage, transportation and disposal of hazardous biological materials and select agents at University of Tennessee campuses.

Definitions:

1. **Biological hazards** - any agents, materials, or conditions that pose a threat to human, animal, plant, or environmental health. Biological hazards may include, but are not necessarily limited to, the following:
    a. **Biological agents** – propagative, typically microscopic, agents that may cause a broad range of disorders or diseases in a host, including acute infections, chronic infections, allergies, and toxicoses, and ranging in severity from asymptomatic to fatal. Examples include bacteria, viruses, fungi, protozoa, helminths, and prions. Biological agents may also be referred to as infectious agents, etiological agents or pathogens.
    b. **Biological toxins** - proteins or other macromolecules, or mixtures thereof (e.g. venoms), derived from biological systems that may cause or contribute to disease. Toxins are non-propagative but may have acute and serious-to-fatal effects.
    c. **Biological vectors** - any living organism that transmits a biological agent or toxin to humans, animals, or plants, typically via biting, feeding, or other mechanical process (e.g. mosquitoes, ticks, fleas, bats, etc.).
    d. **Diagnostic specimens** - Blood, blood products, tissues, secretions, excretions, or cell lines derived from humans or animals, which may be reservoirs of biological agents, toxins, or vectors.
    e. **Environmental samples** - plant, soil, or water samples that may be reservoirs of biological agents, toxins, or vectors.
    f. **Recombinant or synthetic nucleic acid molecules** – molecules that:

i. are constructed by joining one or more naturally-occurring nucleic acid molecules, and which can replicate in a living cell;
ii. are 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; or
iii. result from the replication of those described in (i) or (ii) above.

Recombinant or synthetic constructs that encode toxins, viruses, oncogenes, antibiotic resistance (of clinical relevance), or any other molecule that contributes to disease are of particular concern. Host cells and systems, methods of gene regulation or deregulation, horizontal and vertical genetic transfer, and/or experimental procedures may also contribute to the risk of recombinant/synthetic nucleic acid molecules.

2. **Select Agents** - infectious agents and toxins that are considered by the United States Public Health Service, Department of Health & Human Services (DHHS) or the Department of Agriculture, Animal & Plant Health Inspection Service (USDA APHIS) as having the potential to pose substantial harm or a severe threat to human, animal or plant health or plant products; see current list of select agents and toxins.

Responsibilities:

1. Chancellor or appointed authority, as applicable, shall:
    a. designate a biosafety administrator (e.g. biosafety officer) to ensure that applicable safety and compliance requirements are upheld by each entity that utilizes biological hazards.
    b. establish an institutional biosafety committee (IBC) and biosafety administrator (biosafety officer) for the oversight of research involving recombinant and synthetic acid nucleic acid molecules as per the policy requirements outlined by the *National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*).
    c. designate a responsible official* (RO) if the campus or institute possesses and/or uses select agents or toxins as defined by DHHS (42 CFR Part 73) or USDA APHIS (9 CFR Part 121 and/or 7 CFR Part 331), as required by the Public Health Security and Bioterrorism Preparedness Response Act of

2002. The RO must have the responsibility, authority, and resources to act on behalf of the entity to ensure compliance with the select agent regulations.

*The select agent responsible official may be someone other than the biosafety administrator.

2. Biosafety administrator (e.g. biosafety officer) shall:
    a. establish and implement a framework for oversight of biological hazards and select agents used in research, teaching, and diagnostic testing labs.
    b. uphold compliance with applicable regulations, codes, and institutional policies.
    c. perform risk assessments and provide technical advice to the IBC, RO, faculty, staff, and university administration as required or requested.
    d. perform routine inspections of facilities where biological hazards or select agents are being used or stored to ensure that required safety, containment, and security practices are met.
    e. develop emergency plans for accidental exposures, spills, or environmental releases involving biological hazards or select agents.
    f. report any significant problems, violations, or research, teaching, or diagnostic testing-related accidents or illnesses to the IBC, RO, or other applicable campus administrators.
    g. serve on the IBC as stipulated by the *NIH Guidelines*, as applicable.
    h. conduct an annual evaluation of the compliance and currency of its respective biological safety and select agents program. Program evaluations may be included in the annual University of Tennessee environmental health and safety report at the discretion of the system safety officer

3. Select Agents responsible official shall:
    a. 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.
    b. 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.

c. conduct annual emergency preparedness, spill response, and/or security drills as required.
d. have a physical presence at the University to maintain compliance with the select agent regulations and be able to respond in a timely manner to onsite incidents involving select agents in accordance with the incident response plans.
e. be granted sufficient authority to speak and act on behalf of the University.

4. Institutional Biosafety Committee shall (as required by the *NIH Guidelines*):
    a. review research involving recombinant or synthetic nucleic acid molecules subject to the *NIH Guidelines*.
    b. fulfill and uphold all requirements as described in Section IV-B-2 of the *NIH Guidelines*.
    c. fulfill and uphold other responsibilities appointed at the discretion of the chancellor or appointed authority, which may include, but is not necessarily limited to, the following:
        i. establish, communicate, and monitor policies, practices, and procedures covering biological hazards and select agents.
        ii. require registration of biological hazards and select agents *not subject* to the *NIH Guidelines* (e.g. wild-type biological agents, biological toxins, diagnostic specimens, etc.).
        iii. as allowed by regulation, increase or reduce the safety and containment criteria depending on the circumstances presented by the biological hazard and/or specific procedures.
        iv. investigate and recommend corrective actions for accidents, exposures, illnesses, environmental releases or other adverse events involving biological hazards.
        v. Investigate, and set corrective actions, and establish escalation procedures for violations of applicable policies and/or unacceptable safety or containment practices.
        vi. review and approve design specifications, certification criteria, and safety and security manuals for high-containment laboratories (i.e., BSL-3).

vii. review and assess compliance with permit or license-related requirements for biological hazards subject to USDA APHIS, Food & Drug Administration (FDA), and/or Environmental Protection Agency (EPA) regulations.

viii. 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.

Program:

1. The University of Tennessee system biological safety and select agents program requirements shall comply with all existing state, federal and local codes, ordinances, laws and university policies relating to the transportation, use, generation, storage and disposal of whatever may be determined by those regulations to be biological hazards.

2. The program requirements shall be communicated and available to all campuses, colleges, institutes, departments and persons who may be in contact with biological hazards and/or subject to applicable safety and compliance requirements.
3. The extent of the program at each campus, college, or institute will be determined by the specific biological hazards in use by that entity.
4. Each campus, college, or institute shall comply with the system policy by establishing a written program covering biological hazards and select agents.

Non-Compliance:

In the event of any cited violation by federal, state, or local regulatory agencies, immediate notification and proposed remedy of the same shall be made to the respective campus, college, or institute biosafety administrator and/or responsible official as well as the University of Tennessee system safety officer.

Related Laws, Policies and Procedures:

1. Department of Agriculture, Animal & Plant Health Inspection Service (USDA APHIS)

a. 7 CFR, Parts 300-399 (Plant Protection & Quarantine; Biotechnology Regulatory Services)
b. 9 CFR, Parts 1-199 (Veterinary Services, Center for Veterinary Biologics)

2. Department of Commerce & Foreign Trade
   a. 15 CFR, Part 774 Commerce Control List

3. Department of Transportation Pipeline & Hazardous Materials Safety Administration (DOT PHMSA)
   a. 49 CFR, Parts 171-180

4. Environmental Protection Agency (EPA)
   a. 40 CFR, Part 725

5. International Air Transport Association (IATA)/International Civil Aviation Organization (ICAO)
   a. Dangerous Goods Regulations

6. Occupational Safety and Health Administration (OSHA)
   a. 29 CFR 1910.1030 Bloodborne Pathogens (BBP) Standard
   b. Tennessee Code Annotated 50-3-203(e)(1)-(e)(4) and Tennessee Rule 0800-1-10 (TOSHA addendum to 29 CFR 1910.1030)

7. Public Health Service, Department of Health & Human Services (DHHS)
   a. 42 CFR, Part 71 (CDC Import Permit Program)
   b. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. (BMBL)
   c. NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (v. April 2019)
   d. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

8. Select Agents & Toxins
   a. 7 CFR, Part 331 (USDA APHIS; plant agents)
   b. 9 CFR, Part 121 (USDA APHIS; animal agents)
   c. 42 CFR, Part 73 (DHHS; human agents)
   d. Public Health Security and Bioterrorism Preparedness Response Act of 2002

9. Tennessee Department of Environment & Conservation (TDEC)
   a. Tennessee Rule 0400-11-01 Solid Waste Processing & Disposal

b. Tennessee Rule 0400-11-01-.04(2)(k)(4) Regulated Medical Wastes

Authority and Interpretation:

The University of Tennessee system safety officer is the responsible official for system safety policies. The University of Tennessee, Knoxville biosafety officer is the designated policy owner for policy SA0450 Biological Safety and Select Agents. The policy owner interprets this policy and shall revise or eliminate any or all parts as necessary to meet the changing needs of the University of Tennessee with concurrence of the responsible official and approval of the Senior Policy Review Group.