8.10.1 Select Biological Agents

Chapter 8 - Health & Safety	Original Effective Date: May 2002
Section: 8.10 Select Biological Agents	Date Last Reviewed: May 2021
Responsible Entity: Vice President for Facilities and Capital Planning	Date Last Revised: May 2021

I. Purpose

The purpose of this Policy is to provide guidance in complying with statutes concerning special biological agents and toxins known to be potential terrorist agents (Select Agents). These agents pose a severe threat to public health and safety, to animal health or to animal products. In addition, the medical, educational, legal, administrative, and ethical issues related to specific situations involving these Select Agents and toxins include but are not limited to: Possession (Access to Select Agents), Use (Receipt, Storage, and Disposal) and Transfer (Shipment of Select Agents).

II. Scope

This Policy is applicable to students, faculty, and employees of UT Health San Antonio (University) and shall be made available to students, faculty, and staff members of the University by its inclusion in the student, faculty, and personnel guides if practicable, or by any other method.

III. Policy

The pathogenic agents represented by Select Agents are generally highly virulent and known to cause significant injury or illness in humans. Therefore, scientific, and clinical research must be accessible to find cures for these human diseases. All select agent usage at the University must be reasonable, appropriate, peaceful, and derive a net benefit to society. The Principal Investigator (PI) requesting to use a select agent and the departmental Chair are responsible for determining the peaceful and appropriate use of Select Agents.

All facilities using, storing, handling, or disposing of Select Agents must be restricted from unauthorized access at all times. People from outside the University are prohibited from using or accessing Select Agents. A record or log of all people entering select agent storage areas must be properly maintained. This log may be maintained electronically via access card software. A list of all employees granted access to select agent laboratories will be maintained by the Responsible Official and the UT Health San Antonio Police.

Each year calendar year, University employees who handle, use, or have access to a Select Agent must successfully complete the Annual Statement of Eligibility to Handle Select Biological Agents or Toxins and return it to the UT Health San Antonio Police department. This form is intended to determine if employees who have access to University Select Agents are Restricted Persons.

Pursuant to 18 U.S.C. §175b, Restricted Persons are strictly forbidden to access select biological agents. As an extension, any University employee required to use, store, or dispose of select biological agents as an essential task/function of their employment may not be a Restricted Person.

A. Fines and Criminal Penalties

It is a criminal offense for Restricted Persons to ship, transport, receive, or possess (in interstate or foreign commerce) non-exempt Select Agents. This federal offense is punishable by fine or imprisonment not to exceed ten years. Federal regulations in 42 CFR Part 73 state that individuals in violation of those standards are subject to a fine of no more than $250,000 or one (1) year in jail or both. Violations by organizations are subject to a fine of no more than $500,000 per event. A false, fictitious, or fraudulent statement or representation on government forms required in the part for registration of facilities or for transfers of Select Agents is subject to a fine or imprisonment for not more than five (5) years or both, for an individual; and, fine for an organization.

B. Institutional Reviews

The Institutional Biosafety Committee (IBC) is charged with providing advisory guidance and review of the safety procedures for use, storage, and disposal of Select Agents at the University. Prior to receiving these Select Agent materials at the University, the PI must have an approved research protocol reviewed by the IBC and if applicable, an approved IACUC protocol for animal use. Both the institution and PI must be approved and registered with either the Centers for Disease Control and Prevention (CDC) or the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) for that specific select agent and also be approved by the Responsible Official. All shipments of Select Agents must be reviewed and approved by the Responsible Official prior to shipping or receiving these materials. Law enforcement personnel will review annual statements of eligibility.

C. Disputes

Disputes of findings will be considered by the IBC. If unresolved, the disputes related to use, storage, shipment, or disposal of Select Agents will be referred to the University Executive Committee.

D. Select Agents and Toxins

The University Environmental Health and Safety department maintains the current list of HHS Select Agents and Toxins.

1. Restrictions
    a. The deliberate transfer of, or selection for, a drug resistance trait to Select Agents that are not known to acquire the trait naturally if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.
    b. Experiments involving the deliberate formation of synthetic or recombinant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD [50] < 100 ng/kg body weight.
2. Excluded and Exempt Select Agents and Toxins
    a. Select Agents and toxins that meet the following criteria are excluded from the requirements of the regulations:
        i. A Select Agent or toxin in its naturally occurring environment provided the Select Agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
        ii. Non-viable Select Agents or non-functional toxins.
        iii. A Select Agent or toxin that has been subjected to decontamination or destruction procedure when intended for waste disposal.
        iv. A Select Agent or regulated nucleic acid that can produce infectious forms has been subjected to a validated inactivation procedure and confirmed through a viability testing protocol.
        v. Material containing a Select Agent is excluded when subjected to a procedure that removes all viable Select Agent cells, spores, or virus particles and the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable Select Agent.
        vi. An animal inoculated with or exposed to an HHS select toxin.
        vii. Principal Investigators, Physicians, Veterinarians who maintain acceptable quantities of toxins as listed in 42 CFR 73.
        viii. An attenuated strain, published in the Federal Register, which does not pose a severe threat to public health and safety.
    b. Exemptions for Select Agents or toxins products that bear, or contain listed Select Agents or toxins that are cleared, approved, licensed, or registered under any of the following laws:
        i. The Federal Food, Drug or Cosmetic Act (21 U.S.C. 301 et seq.)
        ii. Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262)

iii. Virus-Serum-Toxin Act (21 U.S.C. 151-159)

iv. Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq)

c. Exemptions for clinical or diagnostic laboratories that possess, use, or transfer a Select Agent or toxin that is contained in a specimen presented for diagnoses, verification or proficiency testing provided that:

i. The Select Agent or toxin are transferred within 7 days (specimens for identification or verification) or 90 days (specimens for proficiency testing) to a registered facility in accordance with 42 CFR 73.16 or destroyed on-site by a recognized sterilization or inactivation process.

ii. The Select Agent or toxin are secured against theft, loss, or release during the period between the identification and transfer or destruction of the Select Agent or toxin.

iii. Identification of a Select Agent is reported to CDC or APHIS other authorities as appropriate.

3. Additional Exemptions

Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of Select Agents maintained by the University's Environmental Health and Safety department. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the Federal Register for review and comment prior to inclusion in this policy.

IV. Definitions

When used in this document with initial capital letter(s), the following words have the meaning set forth below unless a different meaning is required by context.

Restricted Person – an individual who is within any of the categories defined in 18 U.S. Code (U.S.C.) §175b and include, for example, an unlawful user of any controlled substance, an alien illegally or unlawfully in the United States, a fugitive from justice, persons dishonorably discharged from the U.S. Armed Services or nationals of countries determined by the U.S. Secretary of State to have repeatedly provided support for acts of international terrorism.

Select Agent – a biological agent or toxin that has been listed in the Code of Federal Regulations (CFR) 42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121. Select Agents include viruses such as the Ebola and Variola major virus (Smallpox); bacteria such as Bacillus Anthracis and Yersinia pestis; and toxins such as Botulinum neurotoxins and T-2 toxin. The Select Agent & Toxin Listing is provided here.

V. Related References

All related references to governing Laws and Regulation are include in the body of the Policy.

VI. Review and Approval History

A. The approving authority of this policy is the University Executive Committee.

B. The review frequency cycle is set for three years following the last review date, a time period that is not mandated by regulatory, accreditation, or other authority.

Effective Date	Action Taken	Approved By	Date Approved
05/2002	Policy Origination		
05/2013	Policy Revision		
05/2021	Policy Revision, discretionary edits		