SELECT BIOLOGICAL AGENTS POLICY

Overview

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)
- Transfer (Shipment of Select Agents)

This policy is applicable to students, faculty, and employees of the Health Science Center 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.

Definitions

RESTRICTED PERSON: Restricted person is 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 select agent is 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 December 4, 2012 list of these agents is attached.

Policies

The pathogenic agents represented by select agents are generally highly virulent and known to cause significant injury or illnesses in
humans. Therefore, scientific and clinical research must be accessible to find cures for these human diseases. All select agent usage at the Health Science Center must be reasonable, appropriate, peaceful, and derive a net benefit to society. The Principal Investigator 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 Health Science Center 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 Health Science Center University Police.

Each calendar year, a Health Science Center employee who handles, uses, or has access to a select agent must successfully complete the Annual Statement of Eligibility to Handle Select Biological Agents or Toxins and returned to University Police. This form is intended to determine if employees who have access to Health Science Center 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 Health Science Center 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.

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
Institutional Reviews

The Institutional Biosafety Committee is charged with providing advisory guidance and review of the safety procedures for use, storage, and disposal of select agents at the Health Science Center. Prior to receiving these Select Agent materials at the Health Science Center, the Principal Investigator must have an approved research protocol reviewed by the Institutional Biosafety Committee and if applicable, an approved IACUC protocol for animal use. Both the institution and Principal Investigator must be approved and registered with either the CDC or 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.

Disputes

Disputes of findings will be considered by the Institutional Biosafety Committee. If unresolved, the disputes related to use, storage, shipment, or disposal of select agents will be referred to the Health Science Center Executive Committee.

Select Agents and Toxins (As of December 4, 2012)

**HHS Select Agents and Toxins:**

- Abrin
- Botulinum neurotoxins
- Botulinum neurotoxin producing species of Clostridium
- Conotoxins (Short, oaralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)
- Coxiella burnetii
- Crimean-Congo haemorrhagic fever virus
- Diacetoxyescirpenol
Eastern Equine Encephalitis virus

Ebola virus*

Francisella tularensis

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 (Reconstructed 1918 Influenza virus)

Ricin

Rickettsia prowazekii

SARS-associated coronavirus (SARS-CoV)

Saxitoxin

South American Haemorrhagic Fever viruses
  Chapare
  Flexal
  Guanarito
  Junin
  Machupo
  Sabia

Staphylococcal enterotoxins A, B, C, D, E subtypes

T-2 toxin

Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses
  Far Eastern subtype
  Siberian subtype
Kyasanur Forest disease virus

Omsk hemorrhagic fever virus

Variola major virus (Smallpox virus)*

Variola minor virus (Alastrim)*

Yersinia pestis

**Overlap Select Agents and Toxins:**

Bacillus anthracis*

*Bacillus anthracis* Pasteur strain

Brucella abortus

Brucella melitensis

Brucella suis

Burkholderia mallei*

Burkholderia pseudomallei*

Hendra virus

Nipah virus

Rift Valley fever virus

Venezuelan Enquine Encephalitis virus¹

**USDA Select Agents and Toxins:**

African horse sickness virus

African swine fever virus

Avian influenza virus¹
Classical swine fever virus

Foot-and-mouth disease virus*

Goat pox virus

Lumpy skin disease virus

Mycoplasma capricolum¹

Mycoplasma mycoides¹

Peste des petits ruminants virus

Newcastle disease virus¹,²

Rinderpest virus*

Sheep pox virus

Swine vesicular disease virus

**USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins:**

Peronosclerospora philippinensis (Peronosclerospora sacchari)

Phoma glycinicola (formerly Pyrenochaeta glycines)

Ralstonia solanacearum

Rathayibacter toxicus

Sclerophthora rayssiae

Synchytrium endobioticum

Xanthomonas oryzae

* Denotes Tier 1 Agent
Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, and Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3, provided that the individual or entity can verify that the agent is within the exclusion category.

A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

Recombinant and/or Synthetic Nucleic Acids:

1. Nucleic acids that can produce infectious forms of any of the select agents.

2. Nucleic acids that encode for the functional form(s) of the toxins listed, or their toxic subunits.

Other Restrictions:

1. The deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally is if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

2. 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.
Excluded and Exempt Select Agents and Toxins:

1. Select Agents and toxins that meet the following criteria are excluded from the requirements of the regulations:

   - A select agent or toxin in its naturally occurring environment
   - Non-viable select agents or non-functional toxins
   - Principal Investigators, Physicians, Veterinarians who maintain except quantities of toxins as listed in 42 CFR 73
   - An attenuated strain, published in the Federal Register, which does not pose a severe threat to public health and safety

2. 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:

   - The Federal Food, Drug or Cosmetic Act (21 U.S.C. 301 et seq.)
   - Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262)
   - Virus-Serum-Toxin Act (21 U.S.C. 151-159)
   - Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq)

3. 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:

   - 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.

- 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.

- Identification of a select agent is reported to CDC or APHIS other authorities as appropriate

**Additional Exemptions:**

1. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this policy. 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.