

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 8	Health and Safety	Effective:	May 2002
Section 8.10	Select Biological Agents	Revised:	September 2009
Policy 8.10.1	Select Biological Agents Policy	Responsibility:	Vice President for Research

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 persons are defined in 18 U.S. Code (U.S.C.) §175b by the use of eight characteristics and include, for example, illegal aliens, fugitives 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 toxins and T-2 toxin. The November 17, 2008 list of these agents is attached.

EXEMPT SELECT AGENTS AND TOXINS:

1. 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 are exempt:

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 8	Health and Safety	Effective:	May 2002
Section 8.10	Select Biological Agents	Revised:	September 2009
Policy 8.10.1	Select Biological Agents Policy	Responsibility:	Vice President for Research

-
- 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
 - Virus, Serum-Toxin Act (21 U.S.C. 151-159)
 - Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use
2. Exemptions for clinical or diagnostic laboratories that identify the Select Agent provided that they are transferred within 7 days to a registered facility or the select agent is destroyed as outlined in 42 CFR 73.5 and 73.6
 3. Principal Investigators, Physicians, Veterinarians who maintain except quantities of toxins as listed in 42 CFR 73
 4. An attenuated strain which does not pose a severe threat
 5. A select agent or toxin in its naturally occurring environment

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 individual 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 Health Science Center University Police.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 8	Health and Safety	Effective:	May 2002
Section 8.10	Select Biological Agents	Revised:	September 2009
Policy 8.10.1	Select Biological Agents Policy	Responsibility:	Vice President for Research

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](#). This form is intended to determine if employees who have access to Health Science Center select agents are restricted persons.

Each employee must return the [Annual Statement of Eligibility to Handle Select Biological Agents of Toxins](#) to University Police for review and evaluation.

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 72 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.

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. 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

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 8	Health and Safety	Effective:	May 2002
Section 8.10	Select Biological Agents	Revised:	September 2009
Policy 8.10.1	Select Biological Agents Policy	Responsibility:	Vice President for Research

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 November 17, 2008)

HHS Select Agents and Toxins:

Abrin

Botulinum neurotoxins

Botulinum neurotoxin producing species of Clostridium

Cercopithecine herpesvirus 1 (Herpes B virus)

Clostridium perfringens epsilon toxin

Coccidioides posadasii/Coccidioides immitis

Conotoxins

Coxiella burnetii

Crimean-Congo haemorrhagic fever virus

Diacetoxyscirpenol

Eastern Equine Encephalitis virus

Ebola virus

Francisella tularensis

Lassa fever virus

Marburg virus

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 8	Health and Safety	Effective:	May 2002
Section 8.10	Select Biological Agents	Revised:	September 2009
Policy 8.10.1	Select Biological Agents Policy	Responsibility:	Vice President for Research

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

Rickettsia rickettsii

Saxitoxin

Shiga-like ribosome inactivating proteins

Shigatoxin

South American haemorrhagic fever viruses

Flexal

Guanarito

Junin

Machupo

Sabia

Staphylococcal enterotoxins

T-2 toxin

Tetrodotoxin

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)

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 8	Health and Safety	Effective:	May 2002
Section 8.10	Select Biological Agents	Revised:	September 2009
Policy 8.10.1	Select Biological Agents Policy	Responsibility:	Vice President for Research

Yersinia pestis

Overlap Select Agents and Toxins:

Bacillus anthracis

Brucella abortus

Brucella melitensis

Brucella suis

Burkholderia mallei (formerly Pseudomonas mallei)

Burkholderia pseudomallei (formerly Pseudomonas Conotoxins pseudomallei)

Hendra virus

Nipah virus

Rift Valley fever virus

Venezuelan Enquine Encephalitis virus

USDA Select Agents and Toxins:

African horse sickness virus

African swine fever virus

Akabane virus

Avian influenza virus (highly pathogenic)

Bluetongue virus (exotic)

Bovine spongiform encephalopathy agent

Camel pox virus

Classical swine fever virus

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 8	Health and Safety	Effective:	May 2002
Section 8.10	Select Biological Agents	Revised:	September 2009
Policy 8.10.1	Select Biological Agents Policy	Responsibility:	Vice President for Research

Ehrlichia ruminantium (Heartwater)

Foot-and-mouth disease virus

Goat pox virus

Japanese encephalitis virus

Lumpy skin disease virus

Malignant catarrhal fever virus
(Alcelaphine herpesvirus type 1)

Menangle virus

Mycoplasma capricolum subspecies capripneumoniae
(contagious caprine pleuropneumonia)

Mycoplasma mycoides subspecies mycoides small colony (Mmm SC)
(contagious)

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 1

USDA Plant Protection and Quarantine (PPQ)

Select Agents and Toxins:

Peronosclerospora philippinensis (Peronosclerospora sacchari)

Phoma glycinicola (formerly Pyrenochaeta glycines)

Ralstonia solanacearum race 3, biovar 2

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 8	Health and Safety	Effective:	May 2002
Section 8.10	Select Biological Agents	Revised:	September 2009
Policy 8.10.1	Select Biological Agents Policy	Responsibility:	Vice President for Research

Rathayibacter toxicus

Sclerophthora rayssiae var zeae

Synchytrium endobioticum

Xanthomonas oryzae

Xylella fastidiosa (citrus variegated chlorosis strain)

Recombinant Organisms/Molecules:

1. Nucleic acids that can produce infectious forms of any of the select agents.
2. Recombinant nucleic acids that encode for the functional form(s) of the toxins listed, or their toxic subunits.

Other Restrictions:

The deliberate transfer of a drug resistance trait to microorganisms listed that are not known to acquire the trait naturally is prohibited by National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant DNA Molecules", if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

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.
-