

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 8	Health and Safety	Effective:	May 2002
Section 8.10	Select Biological Agents	Revised:	September 2005
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 known to be potential terrorist agents (select agents). In addition, the medical, educational, legal, administrative, and ethical issues related to specific situations involving these select agents:

- Receipt;
- Storage;
- Usage;
- Disposal; and,
- Shipment

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 by the Public Health Service in Appendix A of Title 42 Code of Federal Regulations (CFR) Part 72. Select agents include viruses such as the Ebola and Yellow Fever virus; bacteria such as Bacillus Anthracis and Clostridium botulinum; and toxins such as Botulinum toxins and T-2 toxin. The February 2002 list of these agents is attached.

EXEMPT SELECT AGENTS: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at

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an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR 113 are exempt.

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.

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.

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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 materials at the Health Science Center, an investigator must complete an approved research protocol from the Institutional Biosafety Committee and the Institutional Biosafety Officer. All shipments of select agents must be reviewed and approved by the Institutional Biosafety Officer prior to shipping or receiving these materials. Law enforcement personnel will review annual statements of eligibility. Following institutional approval, Center for Disease Control (CDC) select agent application must also be completed.

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

Viruses:

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses

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4. Equine Morbillivirus
 5. Lassa fever virus
 6. Marburg virus
 7. Rift Valley fever virus
 8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
 9. Tick-borne encephalitis complex viruses
 10. Variola major virus (Smallpox virus)
 11. Venezuelan Equine Encephalitis virus
 12. Viruses causing hantavirus pulmonary syndrome
 13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

Bacteria:

1. Bacillus anthracis
2. Brucella abortus, B. melitensis, B. suis
3. Burkholderia (Pseudomonas) mallei
4. Burkholderia (Pseudomonas) pseudomallei
5. Clostridium botulinum
6. Francisella tularensis
7. Yersinia pestis

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Exemptions: Vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

Rickettsiae:

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

Fungi:

1. *Coccidioides immitis*

Toxins:

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens* epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

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Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

Recombinant Organisms/Molecules:

1. Genetically modified microorganisms or genetic elements from organisms, shown to produce or encode for a factor associated with a disease.
2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any 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. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. § 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. § 2601 et seq.) are exempt.
2. 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.