

Johns Hopkins Safety Manual	<i>Policy Number</i>	HSE 505
<i>Subject:</i>	<i>Last Review Date</i>	09/23/08
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POLICY

The Biosafety Office must review and approve any acquisition (purchase from a vendor or transfer from another entity), possession, and/or use of Select Agents and Toxins at Johns Hopkins University and the Johns Hopkins Hospital and Health System. Nucleic acids that can produce infectious forms of any of the select agent viruses and/or recombinant nucleic acids that encode and/or can be used to express the functional form(s) of any of the select agent toxins are covered under this policy.

SUMMARY

Select agents are bacteria, viruses, toxins, pathogens which have been designated by the Secretary of the U. S. Department of Health and Human Services, and the Secretary of the U. S. Department of Agriculture as having the potential to pose a threat to the public health and safety. Rules concerning the possession, use and transfer of Select Agents and Toxins were enacted by Congress (USA Patriot Act, and the Public Health and Bioterrorism Preparedness Act) in order to regulate the possession, use, and transfer of materials considered highly dangerous or toxic. The governing regulations for this policy are 42 CFR Parts 72 and 73, 42 CFR Part 1003 Possession, Use, and Transfer of Select Agents and Toxins; Final Rule, and 7 CFR Part 331 and 9 CFR Part 121, Agricultural Bioterrorism and Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule. The full text and supporting documentation for these regulations are available at http://www.cdc.gov/od/sap/final_rule.htm. In accordance with the Select Agent and Toxin regulations, the Biosafety Officer and Associate Biosafety Officer have been appointed, respectively, as the Responsible Official and Alternate Responsible Official for Johns Hopkins University and Johns Hopkins Hospital and Health System. The role of these officials is to establish, enforce, and ensure work practices that are compliant with the regulation.

The acquisition/possession of viable Select Agent organisms requires registration with the CDC and the successful completion of a United States Department of Justice security risk assessment. The Biosafety Office is the regulating entity on campus and must be contacted for the latest procedural information on the regulatory requirements for transfer of viable select agent organisms. Individuals who wish to procure Select Agents or Toxins must be approved by the Biosafety Office prior to initiating CDC registration.

The acquisition/possession of Select Agent Toxins does not require registration with the CDC provided that the total quantity possessed by the investigator does not exceed the "excluded quantity" listed in the regulation. Possession and/or use of select agents in excess of the "excluded quantity" without registering with the CDC is illegal. A table of Select Agent Toxins and their excluded quantities is provided below. Please note that "excluded" does not mean "exempt" from the regulation.

The Biosafety Office must be contacted prior to purchasing or otherwise acquiring a Select Agent Toxin. Select agent toxins are commercially available in quantities less than the "excluded quantity" listed in the regulation. The vendor may ask you to sign a statement declaring that Johns Hopkins is exempt from the Select Agent regulation *or* subject to the Select Agent regulation. *These Pre-purchase declarations and other documents concerning Select Agent toxins must be sent to the Biosafety Office.* Transfer of commercially available select agent toxins to off-site locations is prohibited.

The following table lists Select Agent Toxins and their "excluded quantities." This is the maximum quantity you may have in your possession without being required to register with the CDC.

Abrin (100 mg)	Saxitoxin (100 mg)
Botulinum neurotoxins (0.5 mg)	Shigatoxin (100 mg)
<i>Clostridium perfringens</i> epsilon toxin (100 mg)	Shiga-like ribosome inactivating protein (100 mg)
Conotoxin (100 mg)	Staphylococcal enterotoxins (5 mg)
Diacetoxyscirpenol (1000 mg)	Tetrodotoxin (100 mg)
Ricin (100 mg)	T-2 toxin (1000 mg)

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RESPONSIBILITIES

Biosafety Office

- Provide Principal Investigators and purchasing entities the list of HHS and APHIS select agents and toxins.
- Provide templates for compliance-related documentation.
- Register use of select agents and toxins as required by HHS and APHIS regulations
- Approve select agent toxin purchase orders prior to placement
- Maintain a campus-wide inventory of each toxin, its location, and quantity controlled by each Principal Investigator
- Provide training on the regulation.
- Inspect PI records on select agent access.
- Inspect laboratory records and storage area where select agents are located
- Monitor the regulations for changes.
- Communicate changes in regulations to users.
- Amend the policy to reflect changes in the select agent regulation.
- Monitor intra-facility transfer of select agents at Johns Hopkins.

Purchasing Entity

- JHU Purchasing Services and the Core Store will report select agent toxin order requests by fax to the Biosafety Office at 410. 955. 5929.

Principal Investigator

- Maintain a research registration with the Biosafety Office for all research materials, including Select Agent toxins used in active protocols (per HSE 504).
- Attend training on compliance with Select Agent regulation on use, secure storage, security and records.
- Maintain records of select agent and toxin, training, use, inventory, storage, security and destruction of select agents
- Restrict access to select agents and toxins to authorized persons.
- Provide and update as appropriate, a list of the authorized persons to Biosafety Office.
- Notify the Biosafety Office of the following
 - Intent to obtain Select Agents or Toxins, including inventory replenishment.
 - Discovery of missing or unreported inventory.
 - Discovery of unauthorized attempts at access to inventory.
 - Accidental release or laboratory exposure.
- Ensure compliance with policy and regulations by all affiliated personnel.

REVIEW CYCLE

Annual with updates as required.

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HHS SELECT AGENTS AND TOXINS

Items marked with a closed circles (●) are overlap agents that have been listed by both HHS and USDA.

Agents

- Bacillus anthracis
- Brucella abortus
- Brucella melitensis
- Brucella suis
- Burkholderia mallei
(formerly Pseudomonas mallei)
- Burkholderia pseudomallei
(formerly Pseudomonas pseudomallei)
- Botulinum neurotoxin-producing species of Clostridium
- Coccidioides immitis
- Coccidioides posadasii
- Crimean-Congo haemorrhagic fever virus
- Coxiella burnetii
- Ebola viruses
- Eastern equine encephalitis virus
- Francisella tularensis
- Cercopithecine herpesvirus 1 (Herpes B virus)
- Hendra viruses
- Lassa fever virus
- Marburg virus
- Monkeypox virus
- Nipah 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)
- Rickettsia prowazekii
- Rickettsia rickettsii
- Rift Valley fever virus
- South American haemorrhagic fever viruses
 - Flexal
 - Guanarito
 - Junin
 - Machupo
 - Sabia
- 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)
- Venezuelan equine encephalitis virus
- Yersinia pestis

Toxins

- Abrin
- Botulinum neurotoxin
- Clostridium perfringens epsilon toxin
- Conotoxins
- Diacetoxyscirpenol
- Ricin
- Saxitoxin
- Shigatoxin
- Shiga-like ribosome inactivating proteins
- Staphylococcal enterotoxin
- T-2 toxin
- Tetrodotoxin

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USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS

Items marked with a closed circles (●) are overlap agents that have been listed by both HHS and USDA.

Pathogens

- African horse sickness virus
- African swine fever virus
- Akabane virus
- Avian influenza virus (highly pathogenic)
- Bacillus anthracis
- Blue tongue virus (Exotic)
- Bovine spongiform encephalopathy agent
- Brucella abortus
- Brucella melitensis
- Brucella suis
- Burkholderia mallei
(formerly Pseudomonas mallei)
- Burkholderia pseudomallei
(formerly Pseudomonas pseudomallei)
- Botulinum neurotoxin-producing species of Clostridium
- Coccidioides immitis
- Coxiella burnetii
- Camel pox virus
- Classical swine fever virus
- Cowdria ruminantium (Heartwater)
- Eastern equine encephalitis virus
- Foot and mouth disease virus
- Francisella tularensis
- Goat pox virus
- Hendra viruses
- Lumpy skin disease virus
- Japanese encephalitis virus
- Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)
- Menangle virus
- Mycoplasma capricolum/M. F38/M. mycoides Capri (contagious caprine pleuropneumonia)
- Mycoplasma mycoides mycoides (contagious bovine pleuropneumonia)
- Newcastle disease virus (velogenic)
- Nipah virus
- Peste des petits ruminants virus
- Rift Valley fever virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Venezuelan equine encephalitis virus
- Vesicular stomatitis virus (Exotic)

Toxins

- Botulinum neurotoxin
- Clostridium perfringens epsilon toxin
- Shigatoxin
- Staphylococcal enterotoxin
- T-2 toxin

USDA PLANT PATHOGENS

- Candidatus Liberobacter africanus
- Candidatus Liberobacter asiaticus
- Peronosclerospora philippinensis
- Phakopsora pachyrhizi
- Plum Pox Potyvirus
- Ralstonia solanacearum race 3, biovar 2
- Schlerophthora rayssiae var zeae
- Synchytrium endobioticum
- Xanthomonas oryzae pv. oryzicola
- Xylella fastidiosa (citrus variegated chlorosis strain)