

Environmental Health & Safety Policy Manual		
Issue Date: 10/31/2014	Updated: 7/6/2020	Policy # EHS-300.06
Select Agents Policy		

1.0 PURPOSE:

To ensure compliance with Federal regulations for researchers using Select Agents. Select Agents are toxins and pathogens that pose a severe threat to human, animal, and plant health. The lists of these agents are defined by the CDC and USDA, and are included in Appendix A. Certain genetic materials that could be used to produce Select Agents are also regulated – refer to Genetic Regulations citation in Section 7.0.

2.0 SCOPE:

This policy applies to all researchers and laboratories at LSUHSC that intend to acquire and work with Select Agents. LSUHSC does not have a registered Select Agents program currently, but will initiate a program if it becomes necessary. The consequences for failing to adhere to Select Agent regulations and this policy may include termination of research projects and dismissal of position at LSUHSC.

3.0 RESPONSIBILITIES:

Principal Investigators (PI) shall:

- Contact the Biological Safety Officer if planning to obtain Select Agents below the exempt quantities. Submit a Declaration of Toxin Use (Appendix B) and standard operating procedure (SOP) to Environmental Health and Safety for approval. Standard operating procedures shall designate containment equipment, PPE, laboratory hygiene, proper handling of Select Agents, health effects, decontamination, and disposal.
- Contact the Institutional Biosafety Committee (IBC), the Director of the Office of Research Services, and the Biological Safety Officer in writing if planning to obtain Select Agents above the exempt quantities. Note that it can take up to six months for Federal approval to be granted to LSUHSC.
- Register all Select Agents and personnel with the Responsible Official.
- Provide proper training to laboratory personnel using Select Agents.
- Ensure adequate containment equipment and personal protective equipment (PPE) is available.

Institutional Biosafety Committee shall:

- Prior to obtaining Select Agents in excess of exempt quantities, register LSUHSC with the Federal Select Agents Program and designate a Responsible Official and an Alternate Responsible Official using the Federal Select Agents Program [Registration Form](#).
- Review research applications that intend to use Select Agents, toxins, and DNA molecules that encode Select Agent toxins and ensure laboratory facilities are properly equipped for the research.

Environmental Health and Safety Department (EHS) shall:

- Provide technical advice and recommend safety precautions for labs working with Select Agents.

Responsible Official (RO) shall:

- Be accountable for LSUHSC's compliance with the Select Agent regulations.
- Be approved by the Federal Select Agents Program, be familiar with the regulations, have the authority to act on behalf of LSUHSC, maintain and submit the required records, and conduct annual inspections.
- Create and maintain site-specific plans for the biosecurity, biocontainment, biosafety, and incident response of Select Agents and toxins at LSUHSC.
- Undergo a Security Risk Assessment (renewed every three years) and a suitability assessment process if research using Tier 1 Select Agents is to be performed.
- Serve as the main point of contact for all Select Agent registration, reporting, and compliance issues.

Personnel who work with Select Agents shall:

- Be authorized and registered with the RO, and submit to a Security Risk Assessment.
- Complete required training to work with Select Agents.
- Maintain laboratory security.

4.0 PROCEDURES FOR REPORTING, INVESTIGATING, AND ANALYSIS:

Once designated, the Responsible Official makes all reports to the Federal Select Agent Program and conducts investigations. The RO coordinates with the IBC and EHS to manage the LSUHSC Select Agent Program.

5.0 EMPLOYEE TRAINING AND EDUCATION:

The Principal Investigator will provide laboratory-specific training to all laboratory workers on potential hazards before handling, using, or storing Select Agents. Training elements should include awareness of pathogenic effects, selecting the correct PPE, proper decontamination, and standard operating and disposal procedures.

6.0 EXEMPTIONS

Excluded agents and toxins:

Attenuated strains of a Select Agent and inactivate forms of a select toxin, which are excluded from the requirements of Select Agent Regulations. Use of these materials must be declared in the IBC application for research. For more information, see [Select Agent and Toxin Exclusions](#).




Exempt quantities of toxins:

Research laboratories using the following toxins are not required to register with the Select Agent Program, as long as the quantity of toxin is does not exceed the amounts indicated in the table below. Check the [Permissible Amounts](#) to verify there are no changes to the list.

HHS Toxins [§73.3(d)(7)]	Amount
Abrin	1000 mg
Botulinum neurotoxins	1 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol (DAS)	10,000 mg
Ricin	1000 mg
Saxitoxin	500 mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D, and E)	100 mg
T-2 toxin	10,000 mg
Tetrodotoxin	500 mg

- The PI is required to declare the toxin in their IBC application and submit a standard operating procedure to EHS for review and approval.
- The PI is required to keep the toxin under lock and key and keep the laboratory locked when not present.
- The PI must maintain accurate inventory of the toxin to record any purchase, transfer, use, and destruction, and include the toxin with their current [online chemical inventory](#).

7.0 REFERENCES:

- <http://www.selectagents.gov/>
- Select Agents – Genetic Regulations
<http://www.selectagents.gov/guidance-regulation.html>
- [CDC - Possession, Use, and Transfer of Select Agents and Toxins](#)
(42 CFR 73) 
- [USDA - Possession, Use, and Transfer of Biological Agents and Toxins](#)
(7 CFR 331) 
- [Bioterrorism Preparedness and Response Act of 2002](#)
(HR 3448, Public Act 107-188) 

8.0 DEFINITIONS:

Responsible Official (RO) – The individual designated by LSUHSC with the authority to ensure compliance with the Select Agent Regulations at LSUHSC.

Security Risk Assessment – Background check conducted prior to Select Agent registration for personnel working with agents and RO.

Tier 1 Select Agents and Toxins – A subset of select agents and toxins designated in the select agent regulations as “Tier 1” because these agents and toxins are considered to present the greatest risk of deliberate misuse and the most significant potential for mass casualties or deleterious effects on the economy, critical infrastructure or public confidence.

9.0 APPENDICES:

- Appendix A – Select Agent List
- Appendix B – Declaration of Toxin Use

Appendix A – Select Agent List

Note: Refer to: <https://www.selectagents.gov/SelectAgentsandToxinsList.html> for the most recent list.

**HHS and USDA Select Agents and Toxins
7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73**

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. Here is a list of [excluded agents and toxins](#).

HHS SELECT AGENTS AND TOXINS

1. Abrin⁵
2. *Bacillus cereus* Biovar *anthracis**
3. Botulinum neurotoxins^{*,5}
4. Botulinum neurotoxin producing species of *Clostridium**
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X₁CCX₂PACGX₃X₄X₅X₆CX₇)^{1,5}
6. *Coxiella burnetii*
7. Crimean-Congo haemorrhagic fever virus
8. Diacetoxyscirpenol⁵
9. Eastern Equine Encephalitis virus^{3,4}
10. Ebola virus*
11. *Francisella tularensis**
12. Lassa fever virus
13. Lujo virus
14. Marburg virus*
15. Monkeypox virus³
16. 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)
17. Ricin⁵
18. *Rickettsia prowazekii*
19. SARS-associated coronavirus (SARS-CoV)⁴
20. Saxitoxin⁵
- **South American Haemorrhagic Fever viruses:**
 21. Chapare
 22. Guanarito
 23. Junin
 24. Machupo
 25. Sabia
26. Staphylococcal enterotoxins (subtypes A,B,C,D,E)⁵
27. T-2 toxin⁵
28. Tetrodotoxin⁵
- **Tick-borne encephalitis complex (flavi) viruses:**
 29. Far Eastern subtype⁴
 30. Siberian subtype⁴
31. Kyasanur Forest disease virus⁴
32. Omsk hemorrhagic fever virus⁴

33. Variola major virus (Smallpox virus)*
34. Variola minor virus (Alastrim)*
35. *Yersinia pestis**

OVERLAP SELECT AGENTS AND TOXINS

36. *Bacillus anthracis**
37. *Bacillus anthracis* Pasteur strain
38. *Brucella abortus*
39. *Brucella melitensis*
40. *Brucella suis*
41. *Burkholderia mallei**
42. *Burkholderia pseudomallei**
43. Hendra virus
44. Nipah virus
45. Rift Valley fever virus
46. Venezuelan equine encephalitis virus^{3,4}

USDA SELECT AGENTS AND TOXINS

47. African horse sickness virus
48. African swine fever virus
49. Avian influenza virus³
50. Classical swine fever virus⁴
51. Foot-and-mouth disease virus^{*,4}
52. Goat pox virus
53. Lumpy skin disease virus
54. *Mycoplasma capricolum*³
55. *Mycoplasma mycoides*³
56. Newcastle disease virus^{2,3}
57. Peste des petits ruminants virus
58. Rinderpest virus*
59. Sheep pox virus
60. Swine vesicular disease virus⁴

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

61. *Coniothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)
62. *Peronosclerospora philippinensis*
(*Peronosclerospora sacchari*)
63. *Ralstonia solanacearum*
64. *Rathayibacter toxicus*
65. *Sclerophthora rayssiae*
66. *Synchytrium endobioticum*
67. *Xanthomonas oryzae*

*Denotes Tier 1 Agent

¹ C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α -MI and α -GI (shown above) as well as α -GIA, Ac1.1a, α -CnIA, α -CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

² 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.

³ 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), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category.

⁴ For determining the regulatory status of nucleic acids that are capable of producing infectious forms of select agent viruses, please reference guidance at <https://www.selectagents.gov/na-guidance.html>.

⁵ For determining the regulatory status of Recombinant and/or Synthetic nucleic acids that encode for the toxic form(s) of any select toxins if the nucleic acids (i) can be expressed in vivo or in vitro, or (ii) are in a vector or recombinant host genome and can be expressed in vivo or in vitro; please reference guidance at <https://www.selectagents.gov/na-guidance.html>.

Appendix B – Declaration of Toxin Use

Fill out appropriate information, attach the laboratory standard operating procedure, and return to the Biological Safety Officer. For questions regarding SOP creation and risk analysis, contact the Biological Safety Officer.

Principal Investigator: _____
 Department: _____
 Phone/Email: _____
 Source or vendor: _____
 Date of receipt or planned acquisition: _____
 Building/Laboratory Room Number(s): _____

HHS Exempt Toxin	Amount in possession

Has an SOP been developed and reviewed by EHS? _____ If no, please attach SOP.

Is adequate containment equipment and PPE available? _____

Names of personnel who will work with the toxin:

I attest to the fact that these individuals are properly trained regarding safe handling, security, emergency, and accident procedures. I agree to comply with LSUHSC and Federal requirements pertaining to handling, shipment, transfer, and disposal of biological toxins.

 Signature of PI Date

 Biological Safety Officer Date