Environmental Health & Safety Policy Manual		
Issue Date: 10/31/2014	Updated: 12/04/2024	Policy # EHS-300.06
Select Agents and Toxins Policy		

1.0 PURPOSE:

To ensure compliance with federal regulations for researchers possessing Select Agents. The Federal Select Agent Program (FSAP) regulates the possession, use and transfer of select agents and toxins. The lists of these agents and toxins are defined by the CDC and USDA and can be found within the Select Agents and Toxins List. Certain genetic materials that could be used to produce Select Agents are also regulated – refer to the Genetic Regulations citation in Section 7.0.

2.0 SCOPE:

This policy applies to all researchers and laboratories at LSUHSC that intend to acquire or work with Select Agents. Facilities where research with Select Agents and toxins is conducted must be registered with FSAP. 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:

Responsible Official (RO) shall:

- Be accountable for LSUHSC's compliance with the Select Agent regulations.
- Be approved by the FSAP, be familiar with the regulations, have the authority to act on behalf of LSUHSC, maintain and submit the required records, and conduct annual inspections.
- Undergo a Security Risk Assessment (SRA).
- Undergo a suitability assessment process if research using Tier 1 select agents is to be performed.
- Create and maintain site-specific plans for the biosecurity, biocontainment, biosafety, and incident response of Select Agents and toxins at LSUHSC.
- Ensure all individuals listed on LSUHSC's registration have access approval.

- Serve as the main point of contact for all Select Agent registration, reporting, and compliance issues.
- Maintain training records.
- Report as required to the FSAP including any annual investigations, and coordinates with the IBC and EH&S to manage the LSUHSC Select Agent Program.

Alternate Responsible Official (ARO) shall:

- Be able and willing to assume the full range of responsibilities of the RO, should the RO be unable to serve.
- Undergo an SRA.

Principal Investigators (PI) shall:

Contact the Biological Safety Officer (BSO) if planning to obtain a Select Agent *below the exempt quantities*:

- Submit a Declaration of Toxin Use (Appendix A) and standard operating procedure (SOP) to Environmental Health and Safety (EH&S) for approval. SOPs shall designate containment equipment, personal protective equipment (PPE), laboratory hygiene, proper handling of Select Agents and toxins, health effects, decontamination, and disposal.

Contact the Institutional Biosafety Committee (IBC), the Director of the Office of Research Services, and the BSO in writing if planning to obtain a Select Agent *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 RO.
- Provide proper training to laboratory personnel using Select Agents and document training.
- Undergo an SRA.
- Ensure adequate containment equipment and PPE are available.
- Declare the toxin in their IBC application and submit an SOP to EH&S for review and approval.

In addition to the above, the following applies in either instance of planning to obtain Select Agents above or below the exempt quantities, respectively:

- Keep the toxin under lock and key and keep the laboratory locked when no personnel are present.
- Maintain accurate inventory of the Select Agent or toxin to record any purchase, transfer, use, and destruction, and include the toxin with their current online chemical inventory.
- Report all suspected theft, loss, release, or occupational exposure of select agent or toxin to FSAP immediately.

Personnel who work with Select Agents or Toxins shall:

- Be authorized and registered with the RO.
- Undergo an SRA.
- Complete the required training to work with select agents.
- Maintain laboratory biosafety and security.

Institutional Biosafety Committee (IBC) shall:

- Prior to obtaining Select Agents in more than exempt quantities, register LSUHSC with the FSAP and designate an RO and an ARO using the FSAP 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 (EH&S) shall:
Provide technical advice and recommend safety precautions for labs working with Select Agents.

4.0 SECURITY RISK ASSESSMENTS (SRA):

An SRA is the electronic records check performed by the Federal Bureau of Investigation, Criminal Justice Information Service, Bioterrorism Risk Assessment Group (BRAG) to determine whether an entity or an individual who wishes to possess, use or transfer a Select Agent or toxin, or an individual who has been identified by a registered entity as having a legitimate need to access a Select Agent or toxin meets one of the statutory restrictors which would prohibit registration or restrict access. FSAP authorizes access to Select Agents and toxins based on the results of the SRA.

BRAG conducts SRAs of all individuals, ROs, AROs, and non-governmental entities that request access to a Select Agent. An SRA must be renewed every 3 years, within 90 days prior to the expiration date.

Personnel at LSUHSC shall not possess, use, or transfer any Select Agent or toxins without governmental and institutional authority.

5.0 TRAINING REQUIREMENTS:

FSAP-approved individuals that access select agents and toxins must receive information and initial training concerning biocontainment, biosafety, security (including security awareness), and incident response upon approval or prior to entering areas with select agents. The PI 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.

Refresher training must be provided at least annually and whenever significant changes are made to LSUHSC's incident response, biosafety, biocontainment, and/or security plans. If Tier 1 Select Agents are registered at LSUHSC, an annual insider threat awareness briefing on how to identify and report suspicious behaviors must be conducted.

Non-FSAP-approved individuals (e.g., escorted visitors) shall receive training that addresses the hazards of the area they are entering (e.g., laboratory, growth chamber, animal room, storage area, shipping/receiving area, etc.). The training shall consist of components of biocontainment, biosafety, security, and incident response, as it relates to the risks associated with entry into an area where select agents are used and/or stored. For additional information and guidance, see Guidance for Select Agent Regulation Training Requirements. Additionally, the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition provides guidance for laboratories on the safety requirements for working with different diseases and toxins.

6.0 EXCLUSIONS AND EXEMPTIONS:

Select Agents and toxins exclusions:
The Select Agent regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73) established a procedure by which an attenuated strain of a select biological agent or toxin that does not pose a severe threat to public health and safety, animal health, or animal products may be excluded from the requirements of the select agent regulations. The use of these materials must be declared in the IBC application for research. For more information, see Select Agents and Toxins Exclusions.

Select Agents and toxins exemptions:
The Select Agent regulations (9 CFR Part 121) established a procedure by which the Administrator of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service may grant a specific exemption from the select agent regulations, for a showing of good cause, and upon his or her determination that such exemption is consistent with protecting animal health or animal products. If granted, such exemptions are valid for a maximum of 3 years; thereafter, the Administrator may issue a new exemption.

Research laboratories using the following toxins are not required to register with the Select Agent program, if the quantity of toxin does not exceed the amounts indicated in the table below. Check the Permissible Toxin 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

7.0 REFERENCES:

- Federal Select Agent Program – http://www.selectagents.gov/
- Select Agents – Genetic Regulations https://www.selectagents.gov/compliance/guidance/nucleic/regulated.htm
- Select Agents and Toxins (42 CFR 73: Public Health)
- Possession, Use, and Transfer of Select Agents and Toxins (9 CFR 121: Animals and Animal Products)
- Possession, Use, and Transfer of Select Agents and Toxins (7 CFR 331: Agriculture)
- Bioterrorism Preparedness and Response Act of 2002 (HR 3448, Public Law107-188)
- https://www.cdc.gov/orr/dsat/what-is-select-agents.htm
- Security Risk Assessments | Compliance | Federal Select Agent Program

8.0 DEFINITIONS:

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

Select Agents – Biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal or plant products.

Tier 1 Select Agents and Toxins – A subset of select agents and toxins designated in the select agent regulations as "Tier 1" because they present the greatest risk of deliberate misuse with significant potential for mass casualties or deleterious effects on the economy, critical infrastructure or public confidence, and pose a severe threat to public health and safety. See Appendix B for current list.

9.0 APPENDICES:

- Appendix A – Declaration of Toxin Use
- Appendix B – Tier 1 Select Agents and Toxins

Appendix A – Declaration of Toxin Use

Fill out appropriate information, attach the laboratory standard operating procedure, and return it to the Biological Safety Officer. For questions regarding SOP creation and risk analysis, contact the Biological Safety Officer at 504-568-6586 or safety@lsuhsc.edu.

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.

_____

PI Signature Date

_____

Biological Safety Officer Signature Date

LSU Health NEW ORLEANS

Appendix B – Tier 1 Select Agents and Toxins List

Tier 1 Select Agents and Toxins		
HHS Agents and Toxins	**Overlap Agents**	**USDA Agents**
Bacillus cereus Biovar *anthracis* Botulinum neurotoxins Botulinum neurotoxin producing species of *Clostridium* Ebola virus *Francisella tularensis* Marburg virus Variola major virus (Smallpox virus) Variola minor virus (Alastrim) *Yersinia pestis*	*Bacillus anthracis* *Burkholderia mallei* *Burkholderia pseudomallei*	Foot-And-Mouth Disease virus Rinderpest virus