Carnegie Mellon University

Environmental Health and Safety (EHS)
Institutional Biological Safety Committee
Select Agent Program

1.0 Overview

The Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC) and the United States Department of Agriculture (USDA) have regulations for the possession, use, storage, and transfer of biological agents and toxins that could pose a threat to human, animal, and plant health and safety. This procedure is intended for use by all Carnegie Mellon University principal investigators who need to procure, possess, use, store and transfer biological agents and/or toxins as defined by the United States Code of Federal Regulations (CFR), Title 9 and 42. It explains the requirements imposed on you if you wish to procure, use, store, and/or transfer select biological agents and/or toxins.

Carnegie Mellon University's Institutional Biological Safety Committee (IBC) has developed this program to conform to the regulatory conditions implemented by the Public Health Security and Bioterrorism Preparedness Response Act of 2002, which became effective February 7, 2003 with full compliance due before November 12, 2003. The law's purpose is to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The law requires that all persons possessing select biological agents or toxins deemed a threat to public health, animal or plant health, or animal or plant products register with the appropriate federal agency. In addition, the law establishes safety and physical security compliance requirements, exemption criteria, and restrictions upon persons eligible to be granted access to a select agent or toxin in accordance with the United States Patriot Act. More information about the Select Agent Program may be found on The Federal Select Agent Program website.

2.0 Scope

The purpose of this program is to ensure that all federally regulated select agents at Carnegie Mellon University facilities are handled safely, secured properly, and registered with the CDC and/or USDA, Animal Plant Health Inspection Service (APHIS). The program describes requirements for the receipt, possession, use, or transfer of select agents. These requirements are designed to protect against misuse of Select Agents. Receipt, possession, use, transfer or disposal of these agents may not occur without approval of the Responsible Official of the university. This program applies to university faculty, staff, students, and visitors who receive, possess, use, transfer, destroy or dispose select agent(s) while participating in any university-sponsored activity on university property.

3.0 Definitions

(1) *Access*: means the freedom or ability to obtain or make use of select agents. Only authorized persons are permitted access to select agents. Access to a select agent can be limited by either security containers or by escorts. For non-laboratory functions including routine cleaning, maintenance and repairs, non-approved individuals shall be escorted and monitored by an authorized person while accessing areas where select agents are accessible.

(2) *Authorized person*: is an individual who has been approved for access to select agents through the successful completion of a Federal Bureau of Investigation (FBI) security risk assessment.

(3) *Biological agent*: means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

(4) *Entity:* means any government agency (Federal, State or Local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity. For purposes of this policy, the entity is Carnegie Mellon University.

(5) *Extramural transfer*: means to transfer a select agent from a registrant of Carnegie Mellon University to a registrant of another institution. Note: This includes transfers for registrants that are one in the same person and having different institutional privileges.

(6) *Intramural transfers*: means to transfer a select agent from a registrant of Carnegie Mellon University to another registrant of Carnegie Mellon University.

(7) *Overlap select agent*: means a biological agent included in the Code of Federal Regulations Title 9 Part 121.3 and Title 42 Part 73.5

(8) *Overlap select toxin*: means a toxin included in the Code of Federal Regulations Title 9 Part 121.3 and Title 42 Part 73.5

(9) *Principal Investigator (PI)*: is the individual who is designated by the university to direct a project or program and who is responsible to the university for the scientific and technical direction of that project or program

(10) *Responsible official (RO)*: is the individual designated by the university to act on its behalf and who has the authority and control to ensure compliance with the regulations applicable to select agents and toxins. For the purposes of this program, the RO is the university's Biosafety Officer.

(11) *Restricted person*: as defined by the USA Patriot Act of 2001 means any individual who:

- is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
- has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
- is a fugitive from justice;
- is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));
- is an alien illegally or unlawfully in the United States;
- has been adjudicated as a mental defective or has been committed to any mental institution;
- is an alien (other than an alien unlawfully admitted for permanent residence) who is a national of Cuba, Iran, Iraq, Libya, North Korea, Sudan or Syria, or any other country to which the Secretary of State, pursuant to applicable law, has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism;
- has been discharged from the Armed Services of the United States under dishonorable conditions.

Restricted persons are prohibited from having access to select agents

(12) *Select agent*: means a biological agent or toxin deemed a threat to the public, animal, or plant health, or to animal or plant products and included in the Code of Federal Regulations Title 9 Part 121.3 and Title 42 Part 73.4

(13) *Select toxin*: means a toxin included in the Code of Federal Regulations Title 9 Part 121.3 and Title 42 Part 73.4

(14) *Toxin*: means the toxic material or product of plants, animals, microorganisms (including, but not limited to bacteria, viruses, fungi, rickettsiae or protozoa) or infectious substances, or recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

4.0 Roles and Responsibilities

4.1 Responsible Official

The Director of EHS is the Responsible Official (RO) for Carnegie Mellon University. All activities involving the registration with federal agencies, intramural or extramural transfers, disposal, and exclusion or exemption from federal regulation must be coordinated through the university's Department of Environmental Health and Safety (EHS) and reviewed and approved by the RO. The RO submits all applications to the CDC and/or USDA.

4.2 Principal Investigator

The Principal Investigator (PI) is responsible to direct a project or program involving select agents in compliance with all regulatory requirements set forth. The PI is responsible to the university for the scientific and technical direction of the project or program.

4.3 Authorized persons

Authorized persons with access to select agents are required to attend special training from the RO prior to handling select agents and follow prescribed work practices. Authorized persons must handle Select Agents safely, secure them properly when they are not in use, update inventories regularly and dispose of materials appropriately when work is completed.

4.4 Restricted persons

Restricted persons are prohibited from having access to select agents.

5.0 Procedures

5.1 Determination

Select agents are those infectious agents, biologically-derived toxins, and those genetic elements from any select agent containing nucleic acid sequence(s) which, if inserted into an appropriate host system are reasonably believed capable of producing disease or toxicosis.

(1) All materials that are known to or reasonably suspected of containing one of the select agents, including tissue samples, unless exempted as a human or veterinary clinical specimen, are subject to this regulation

(2) This procedure covers all research involving the possession, use, *ex vivo* and *in vivo*, transfer, destruction, and disposal of select agents at Carnegie Mellon University.

(3) All users of select agents at the university must comply with the defined procedures for use of select agents. Failure to comply will result in prohibition of further use and confiscation of said substances. Additionally, any violations of procedures for use of select agents may result in disciplinary action up to and including termination.

A list of Select Agents as of November 2021 is found in **Table 1**: ***Select Agent List*** and the reader should consult CDC and USDA websites for current listings.

Note: Federal law provides that in the case of violations of the law, individuals are subject to federal criminal penalties, to include prison and fines.

5.2 Select Agent Registration

All requests to receive, possess, use, or transfer a select agent at the university must be for valid research purposes and shall be submitted to the university's RO and Vice Provost for Research for review and his/her approval. The university's RO shall determine all applicable regulatory requirements.

5.2.1 Select Agent Registration with the University

PI's considering working with any select agent material must review section 5.7 *Procurement* and complete **BS2.2 form 1, *Select Biological Agent and/or Toxin Registration Application*** and submit it to the RO. ***This applies to exempt select agents as well as those that require federal registration.***

5.2.2 Select Agent Registration with the CDC/APHIS

PI's who fall under federal regulation, must register their intent to use select agent material with the CDC and/or APHIS ***prior*** to bringing select agent materials to the university. PI's, in collaboration with the RO, must complete the application packet. The RO will then submit the application to the CDC and/or APHIS.

5.3 Exemption/Exclusion

PIs shall defer the determination of an exemption and the appropriateness of an exclusion request to the university's RO.

5.3.1 Regulatory Exemption

Certain select agent materials that meet regulatory criteria are exempt from registration with the CDC and/or APHIS. A list of exemptions can be found in **Table 2: *Select Agent Exemptions***. In addition to registering with EHS, investigators possessing toxins, in quantities below the applicable limits, listed in Table 2 must sign and date **BS2.2 form 2, *Select Agent Exemption Declaration***.

To ensure regulatory compliance, EHS requires PIs to maintain an inventory logbook to document quantities, use, and destruction of exempt select agent toxins. Select agent toxins may not be destroyed until all applicable forms of **BS2.3 Destruction of Select Agents** documenting the method of destruction, have been submitted by the PI to the RO for his/her approval.

5.3.2 Specific Exclusion Request

PI's in collaboration with the RO, may request specific exclusion of materials they do not consider to fall under federal regulation. A current list of attenuated strains of select biological agents and toxins that are excluded from the Act can be found at the CDC website and the APHIS website, respectively.

PIs must submit the exclusion request to the RO who will review the request and submit it to the CDC and/or APHIS if deemed appropriate. Exclusion requests to CDC or APHIS must be processed and signed by the RO. Exclusion requests are evaluated by CDC or APHIS on an individual basis. The request may be granted if the agency determines the material does not pose a significant public health or safety threat.

5.4 Personnel Security Risk Assessment

Prior to working with or having access to select agents requiring registration with the CDC and/or APHIS, all individuals must undergo a security risk assessment by the FBI.

5.5 Training

Select Agent training is required for authorized persons from the RO.

5.6 Security

Stored select agents must be secured in a locked container. The containers must be kept locked at all times. If lock boxes are used, they must be affixed to the refrigerator/freezer/cabinet. Select agents not in storage must be controlled and maintained under constant surveillance.

5.7 Procurement

Select agent procurement requires a PI to have an approved **BS2.2 form 1, *Select Biological Agent and/or Toxin Registration Application*** and a **BS2.2 form 3, *Procurement Request to Purchase a Select Biological Agent and/or Toxin***. ***This applies to exempt select agents as well as those that require federal registration.***

5.8 Documentation

The RO shall:

(1) Maintain and implement a comprehensive program that ensures compliance with federal regulation applicable to select agents.

(2) Keep an up-to-date accurate list of all individuals approved for select agent access.

(3) maintain records pertaining to inspections, training, transfers of select agents, destruction and/or disposal of select agents, and incidents associated with select agents

(4) Develop and implement safety, security, and emergency response plan

(5) Coordinate the removal of all remaining select agent or toxin and/or its waste upon the request of an authorized person. When the agent or toxin's use is complete, the inventory balance for an individual shipment is verified by the RO or his/her designate and the **BS2.2 form 4, *Procurement Inventory for Select Biological Agent and/or Toxin*** is collected. Any remaining material is collected from the laboratory and secured until an appropriate destruction mechanism may be employed by the RO or his/her designate.

PIs shall:

(1) Maintain current and accurate Select Agent inventory as described in the relevant regulation. **This applies to exempt select agents as well as those that require federal registrations**. PIs shall utilize **BS2.2 form 4, *Procurement Inventory for Select Biological Agent and/or Toxin***. The inventory is a continual record that is maintained from receipt to disposal or destruction and includes the following:

- type of select agent and/or toxin
- manufacturer of select agent and/or toxin,
- lot number
- quantity at receipt
- date received
- dates of withdrawal and respective quantities withdrawn
- description of use for each withdrawal
- final disposition of select agent and/or toxin (e.g. transfection, radiolabeled, waste, etc.) and respective quantities.

(2) Maintain log(s) as described in the relevant regulation to track all persons who enter the area where federally registered select agents are used or stored. The log(s) must record the time of entry and exit for all authorized persons, and other individuals, along with the name of the authorized person who escorted the unapproved individual.

All records, inventories, and logs must be kept for a minimum of 3 years.

5.9 Transfers

All transfers of select agents require prior authorization of the transferor's and recipient's RO.

(1) Intramural transfer of select agents must be approved by the university's RO before the transfer occurs.

(2) Extramural transfers of select agents require the prior authorization of the university's RO and the RO at the facility of the recipient.

5.10 Destruction and Disposal

Destruction and disposal of select agents must be done in accordance with federal procedures. Select agents may not be destroyed until all applicable forms of **BS2.3 Destruction of Select Agents** documenting the method of destruction, have been submitted by the PI to the RO for his/her approval.

For all federally regulated select agents, the RO shall notify the appropriate federal agency five (5) working days in advance of destruction of any select agent.

6.0 Destruction of Select Agents

6.1 Scope

This Standard Operating Procedure (SOP) provides a summary of requirements for destruction of Select Agents that are regulated pursuant to 9 CFR 121, and 42 CFR 73. **Federal law requires that the**

university's Responsible Official (RO) notify the Center for Disease Control (CDC) and/or Animal Plant Health Inspection Service (APHIS) in advance of the destruction of registered Select Agent organisms or toxins. This notification shall be coordinated through the Department of Environmental Protection (EHS).

Requirements for destruction are dependent on the type of work conducted and/or the purpose of the destruction, and are described below. As an alternative to destruction, Select Agents may be transferred to a registered facility. All transfers must be conducted in consultation with EHS. Refer to **BS 2.2 Select Agent Program**.

6.2 Notification of the Proposed Destruction of Select Agents

Complete the BS 2.3 Form 1, *Notification of Proposed Destruction of Select Agents* when proposing to destroy Select Agent organisms and/or toxins. Submit the completed form to the Biosafety Office, MI 313, at least ten (10) working days in advance of the proposed destruction date. The Biosafety Officer (BSO) will notify the CDC or APHIS of the proposed destruction. Once the proposed destruction is approved by the respective agency, the BSO will notify the PI. Call the Biosafety Office if you have any questions.

7.0 Bacteria and Viruses

7.1 Working Cultures

When destroying working cultures of Select Agent organisms, it is not necessary to notify EHS, CDC or APHIS. However, working cultures must be destroyed immediately after use. Accumulation of Select Agent organisms in infectious waste bags or sharps containers is prohibited.

7.2 Stock Cultures

When a laboratory intends to destroy all of its stock of a Select Agent organism, CDC or APHIS must approve the destruction prior to its occurrence. Follow the steps below to destroy Select Agent organism stock cultures.

(1) Complete and submit the BS2.3 Form 1, *Notification of Proposed Destruction of Select Agents* to EHS.
(2) BSO will notify the PI when destruction is approved and arrange a time to serve as witness to the destruction.
(3) Use steam sterilization (autoclave) for destruction of bacteria and viruses. Autoclave organisms for a minimum of 1 hour at 121°C.
(4) Document the destruction of Select Agent organisms in the laboratory's Select Agent Inventory logbook.
(5) Dispose of all autoclaved Select Agent organisms as infectious waste.

8.0 Toxins

Toxins may be destroyed by several methods as shown in Table 1. Some toxins are inactivated by autoclaving for one hour at 121°C. Others are inactivated by exposure to sodium hypochlorite and/or sodium hydroxide.

8.1 Chemical destruction of toxins

When using sodium hypochlorite and/or sodium hydroxide to destroy toxin, the procedure(s) must be performed in a laboratory chemical fume hood or a biological safety cabinet. At a minimum, personal protective equipment for all procedures should include long sleeved protective clothing, gloves, and eye protection.

(1) Complete and submit the BS2.3 Form 1, *Notification of Proposed Destruction of Select Agents* to EHS.
(2) BSO will notify the PI when destruction is approved and arrange a time to serve as witness to the destruction.
(3) Work in a chemical fume hood or biosafety cabinet with sash at height for safe and effective work.
(4) Place plastic backed absorbent paper on the work surface of the fume hood or biosafety cabinet.
(5) Put the select agent into solution in a primary container. Do not use glass for a primary container.
(6) Place the primary container in a secondary container (e.g. beaker or rack).
(7) Slowly dispense an equal volume of the concentrations of sodium hypochlorite and/or sodium hydroxide designated in Table 1 into the primary container of toxin solution to be destroyed.
(8) Do not replace the cap on primary container.
(9) Place a "WARNING/DO NOT USE" sign on the hood/cabinet.
(10) Allow a minimum of 30 minutes exposure time. (See Table 1 for additional exposure time recommendations)
(11) Document the destruction of Select Agent toxin in the laboratory Select Agent inventory logbook.
(12) Secure the cap on the primary container. DOUBLE BAG the material in zip-lock plastic bags and label it "Inactivated/denatured (TOXIN NAME)"
(13) Submit a request to dispose as hazardous waste.

8.2 Steam sterilization (Autoclaving) of Toxins

If acceptable as a method in Table 1, destroy toxins by autoclaving them using the procedure outlined below.

(1) Complete and submit the **BS2.3 Form 1, *Notification of Proposed Destruction of Select Agents*** to EHS.
(2) BSO will notify the PI when destruction is approved and arrange a time to serve as witness to the destruction.
(3) In a chemical fume hood or biological safety cabinet, loosen the cap of the primary toxin container to allow steam penetration
(4) Place the primary container into a secondary biohazard sharps container.
(5) Place the sharps container in an autoclave pan.
(6) Autoclave at 121°C for 1 hour on liquid cycle (slow exhaust).
(7) Document the destruction of Select Agent toxin in the laboratory Select Agent inventory log book.
(8) After autoclaving, allow time for materials to cool before handling.
(9) Discard the sharps container and its contents as infectious waste.

Note: *Do not use steam sterilization for the destruction of any low molecular weight toxins (e.g. mycotoxins, marine and reptile venoms)*.

All wastes from toxins that is not disposed as infectious waste must be collected for disposal as hazardous waste.

8.3 Table 1: Inactivation Procedures for Select Agent Toxins

Allow at least 30-minute chemical contact time for complete inactivation of toxin. Any procedure labeled "Y" is an approved procedure for inactivation of the toxin specified. Any procedure labeled "N" is not an approved procedure for inactivation of the toxin specified.

Select Agent Toxin	**Steam Sterilization**	**Chemical Destruction**			
	1 hour@ 121°C, liquid exhaust	***2.5% NaOCL + 0.25 M NaOH***	***NaOCl***		
			0.1%	1.0%	2.5%
Abrin[1]	Y	N	N	N	N
Botulinum Neurotoxin [1, 4]	Y	Y	Y	Y	Y
Clostridium perfringens epsilon toxin	Y	N	N	N	N
Conotoxin	Contact BSO for details				
Diacetoxyscirpenol	N	Y	N	N	+ (3-5%)
Ricin[1, 3]	Y	Y	Y	Y	Y
Saxitoxin[1, 3]		Y	Y	Y	Y
Shigatoxin & Shiga-like ribosome inactivating Proteins	Y	Y	Y	Y	Y
Staphylococcal Enterotoxins[1, 3]	Y	Y	Y	Y	Y
Tetrodotoxin[1, 3]	N	Y	N	Y	Y
T-2 Toxin[1, 2]	N	Y	N	N	N

[1]Wannemacher R.W. 1989. Procedures for Inactivation and Safety Containment of Toxins. Proc. Symposium on Agents of Biological Origin, U.S. Army Research, Development and Engineering Center, Aberdeen proving Ground, MD. pp. 115-122.

[2]For complete inactivation of T-2 mycotoxin extend exposure time for all liquid samples, accidental spills, and non-burnable waste in 2.5% sodium hypochlorite and 0.25 N sodium hydroxide for 4 hours. Expose cages and bedding from animals exposed to T-2 mycotoxin to 0.25% sodium hypochlorite and 0.025 N sodium hydroxide for 4 hours.

[3]For inactivation of saxitoxin, tetrodotoxin, ricin, botulinum toxin, or staphylococcal enterotoxins, expose work surfaces, working solutions, equipment, animal cages and spills to 1.0% sodium hypochlorite for 30 minutes.

9.0 Revisions

Date	Documented Changes	Initials
June 2017		
May 2021	Updated Format and Accessibility Update	MAS
Nov, 3, 2021	Updated content (removed an outdated reference)	MAS
April 2022	Updated content and formatting	KAA
August 2023	Reviewed – no updates needed	AL
August 2024	Reviewed – no updates needed	AL

10.0 Forms

10.1 Notification of the Proposed Destruction of Select Agents Form

Carnegie Mellon University requires all principal investigators who wish to destroy biological agents and/or toxins specified in **Table 1: Select Agent List of BS2.2 Select Agent Program** to complete this form. Complete this form seven days in advance of destroying select agents and/or toxins and return the form to the Biosafety Office, 311 Mellon Institute.

Principal Investigator:		
Email:	**Phone:**	**Fax:**
Lab Manager:		
Email:	**Phone:**	**Fax:**
Department:	**Laboratory location (building, room):**	
Select Agent Name:		
For Toxin give Quantity and Concentration:		
Use: ☐Research ☐Diagnostics ☐Production ☐Other, describe:	**Exemption Status**: ☐42 CFR 73 Exempt ☐42 CFR 73 Non-exempt **Registration:** ☐42 CFR 73 Registered ☐Not registered	
Proposed Destruction Procedure (see **Biosafety Procedure 2.3 Destruction of Select Agents):**		
Planned Date of Destruction (must be ≥ 7 working days after submission date):	**Today's Date**	
Responsible Official Signature:	**Biological Safety Office Approval Date:**	

10.2 Procurement Request to Purchase a Select Biological Agent and/or Toxin

All requests for the receipt of biological agents and/or toxins as specified in **Table 1: Select Agent List** of **BS2.2 Select Agent Program** must be processed with this form. Complete and return the form to the Biosafety Office, 313 Mellon Institute.

Request Date: _____

Requestor Information

Principal Investigator: _____

Laboratory Location: _____

Laboratory Phone Number: _____

Office Phone Number: _____

Delivery Date: _____

Vendor Information

Vendor: _____

Vendor Address: _____

_____

_____

Quantity	Catalog Number	Descriptive Name	Unit Quantity (mg)	Unit Price ($)	Total Price ($)

Payment Information:

Method of Payment:

Purchase Order: ☐

PO Number: _____

Please Attach PO

Credit Card: ☐

Credit Card Number: _____

Credit Card Expiration Date: _____

Name as it appears on the credit card:

_____

_____ _____

Principal Investigator Signature ***Date***

Biological Safety Office:

Select Agent Authorization (SA) Number:_____

□ Exempt from the requirements of the regulation. The principal investigator does not, at any time, have any more that the aggregate amounts listed in 42 CFR 73.4 and 42 CFR 73.5 for each agent under the control of a single principal investigator

□ Subject to the requirements of the regulation. The principal investigator has control of aggregate amounts of listed agents that are above the exempted quantities. CDC Registration Number:

_____ _____

Biosafety Officer Signature ***Date***

10.3 Procurement Inventory for Select Biological Agent and/or Toxin

All PIs must maintain an inventory as specified in **BS2.2 Select Agent Program**. In each laboratory the Procurement Inventory shall be maintained for all biologicals and/or toxins listed in **Table 1: Select Agent List**. The inventory shall contain the type of agent and/or toxin, noting the manufacturer, lot number, quantity at receipt, date received, dates of withdrawal and respective quantities withdrawn, description of use for each withdrawal, and final disposition of agent and/or toxin (e.g. transfection, radiolabeled, waste, etc.) and respective quantities. In short, a continual record must be maintained from receipt to disposal or destruction.

The Biosafety Office removes all remaining agent or toxin and/or its waste upon the request of the authorized person. When the agent or toxin's use is complete, the inventory balance for an individual shipment is verified by the biosafety office and the inventory form is collected. Any remaining material is collected from the laboratory and secured until an appropriate destruction mechanism may be employed by the biosafety office.

Agent or Toxin:_____

Manufacturer: _____

Lot Number: _____

Quantity Received (mg):_____

Receipt Date: _____

Withdrawal Date	**Quantity (mg)**	**Description of Use**	**Final Disposition (mg)**			
			Constructive research *(E.g. transfection, radiolabeled, etc.)*	**Waste**		
				Liquid	*Solid*	*Other (specify)*

Transfer Documentation:

Transfer Date	Quantity Transferred (mg)				
	Original agent and/or toxin	*Modified agent and/or toxin*	***Waste***		
			Liquid	*Solid*	*Other (specify)*

_____ _____
Principal Investigator Signature Date

_____ _____
Biosafety Officer Signature Date

11.0 Appendices

Appendix A HHS and USDA Select Agents and Toxins

7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS	OVERLAP SELECT AGENTS AND TOXINS
Abrin	*Bacillus anthracis*
Bacillus cereus Biovar *anthracis*	*Bacillus anthracis* Pasteur strain
Botulinum neurotoxins	*Brucella abortus*
Botulinum neurotoxin producing species of *Clostridium*	*Brucella melitensis*
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)	*Brucella suis*
Coxiella burnetii	*Burkholderia mallei*
Crimean-Congo haemorrhagic fever virus	*Burkholderia pseudomallei*
Diacetoxyscirpenol	Hendra virus
Eastern Equine Encephalitis virus	Nipah virus
Ebola virus	Rift Valley fever virus
Francisella tularensis	Venezuelan equine encephalitis virus
Lassa fever virus	**USDA VETERINARY SERVICES (VS) SELECT AGENTS AND TOXINS**
Lujo virus	African horse sickness virus
Marburg virus	African swine fever virus
Monkeypox virus	Avian influenza 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)	Classical swine fever virus
Ricin	Foot-and-mouth disease virus
Rickettsia prowazekii	Goat pox virus
SARS-associated coronavirus (SARS-CoV)	Lumpy skin disease virus
SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors	*Mycoplasma capricolum*
Saxitoxin	*Mycoplasma mycoides*
South American Hemorrhagic Fever viruses:	Newcastle disease virus
Chapare	Peste des petits ruminants virus
Guanarito	Rinderpest virus
Junin	Sheep pox virus
Machupo	Swine vesicular disease virus
Sabia	**USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS**

Staphylococcal enterotoxins A,B,C,D,E subtypes	*Coniothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)
T-2 toxin	*Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)
Tetrodotoxin	*Ralstonia solanacearum*
Tick-borne encephalitis complex (flavi) viruses:	*Rathayibacter toxicus*
Far Eastern subtype	*Sclerophthora rayssiae*
Siberian subtype	*Synchytrium endobioticum*
Kyasanur Forest disease virus	*Xanthomonas oryzae*
Omsk hemorrhagic fever virus	
Variola major virus (Smallpox virus)	
Variola minor virus (Alastrim)	
Yersinia pestis	

Appendix B Select Biological Agent and/or Toxin Registration Application

Carnegie Mellon University requires all principal investigators in possession of biological agents and/or toxins specified in **Table 1: Select Agent List** of **BS2.2 Select Agent Program** to complete this form. Complete and return the form to the Biosafety Office, 311 Mellon Institute.

Principal Investigator: _____ Department: _____

I am using a Select Agent(s) as part of a proposed research project at the university as indicated by an "X" in the box adjacent to the respective agent(s) listed below.

Viruses	**Toxins**
□ African horse sickness virus	□ Abrin
□ African swine fever virus	□ Botulinum neurotoxins
□ Akabane virus	□ *Clostridium perfringens* epsilon toxin
□ Avian influenza virus (highly pathogenic)	□ Conotoxins
□ Blue tongue virus (exotic)	□ Diacetoxyscirpenol
□ Camel pox virus	□ Ricin
□ Cercopithecine herpes virus (Herpes B virus)	□ Saxitoxin
□ Classical swine fever virus	□ Shigatoxin and Shiga-like ribosome inactivating
□ Crimean-Congo hemorrhagic fever virus	□ Staphylococcal enterotoxins
□ Eastern equine encephalitis virus	□ Tetrodotoxin
□ Ebola viruses	□ T- 2 toxin
□ Foot and mouth disease virus	**Bacteria**
□ Goat pox virus	□ *Bacillus anthracis*
□ Japanese encephalitis virus	□ Botulinum neurotoxin producing strains of *Clostridum*
□ Lassa fever virus	□ *Brucella abortus*
□ Lumpy skin disease virus	□ *Brucella melitensis*
□ Malignant catarrhal fever	□ *Brucella suis*
□ Marburg virus	□ *Burkholderia mallei*
□ Menangle virus	□ *Burkholderia pseudomallei*
□ Monkeypox virus	□ *Cowdria ruminantium* (Heartwater)
□ Newcastle disease virus (exotic)	□ *Francisella tularensis*
□ Nipah and Hendra complex viruses	□ *Liberobacter africanus*
□ Peste des petits ruminants	□ *Liberobacter asiaticus*
□ Plum pox potyvirus	□ *Mycoplasma capricolum* / M. F38/ M. mycoides capri (contagious caprine pleuropneumonia)

□ Rift Valley fever virus	□ *Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia agent)
□ Rinderpest virus	□ *Ralstonia solanacearum* Race 3
□ Sheep pox	□ *Xanthomonas oryzae* pv. oryzicola
□ South American haemorrhagic fever viruses:	□ *Xylella fastidiosa* (citrus variegated chlorosis)
□ Junin	□ *Yersinia pestis*
□ Machupo	**Rickettsiae**
□ Sabia	□ *Coxiella burnetii*
□ Flexal	□ *Rickettsia prowazekii*
	□ *Rickettsia rickettsii*
Viruses	**Fungi**
□ Guanarito	□ *Coccidioides immitis*
□ Swine vesicular disease virus	□ *Coccidioides posadasii*
□ Tick-borne encephalitis complex (flavi) viruses:	□ *Peronosclerospora philippinensis*
□ Central European Tick-borne encephalitis	□ *Phakopsora pachyrhizi*
□ Far Eastern Tick-borne encephalitis (Russian Spring and Summer encephalitis)	□ *Sclerophthora rayssiae var zeae*
□ Kyasanur Forest disease	□ *Synchytrium endobioticum*
□ Omsk Hemorrhagic Fever	**Prions**
□ Variola major virus (Smallpox virus)	□ Bovine spongiform encephalopathy
□ Variola minor (Alastrim)	
□ Venezuelan equine encephalitis virus	
□ Vesicular stomatitis virus (exotic)	

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms Considered as Select Agents

□ Genetically modified microorganisms or genetic elements from organisms listed above, which are shown to produce or encode for a factor associated with a disease.

□ Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the listed toxins if the nucleic acids: a) are in a vector or host chromosome; b) can be expressed in vivo or in vitro; or c) are in a vector or host chromosome and can be expressed in vivo or in vitro.

□ Listed viruses, bacteria, fungi, and toxins that have been genetically modified.

□ Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to the listed agents that are not known to acquire the trait naturally, it such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

□ Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of listed toxins lethal for vertebrates at an LD50 < 100 ng/Kg body weight.

Biological Safety Office

Select Agent Authorization Number (SA): _____

□ Exempt from the requirements of the federal regulation. The principal investigator shall not, at any time, have any more than the aggregate amounts listed in the federal regulation for each agent under his/her control.

□ Subject to the requirements of the federal regulation. The principal investigator shall have control of aggregate amounts of listed Select Agents that are above the exempted quantities. CDC Registration Number: _____

_____ _____

Biosafety Officer Signature Date

Appendix C SELECT AGENT EXEMPTIONS

Viruses

The following vaccine strains of viral agents are exempt:

- 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

Toxins

Under federal regulations, certain listed toxins are exempt from the federal regulations provided that the principal investigator does not at any time possess more than a specified aggregate amount of any toxin in the purified form or in combinations of pure and impure forms. The specified aggregate amount is designated in parenthesis adjacent to the respective toxin.

1. Abrin **(100 mg)**
2. Botulinum neurotoxins **(0.5 mg)**
3. Diacetoxyscirpenol **(1,000 mg)**
4. Ricin **(100 mg)**
5. Saxitoxin **(100 mg)**
6. Short, paralytic alpha conotoxin containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7 (100 mg)
7. Staphylococcal enterotoxins **(5 mg)**
8. Tetrodotoxin **(100 mg)**
9. T- 2 toxin **(100 mg)**

Bacteria

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

Additional Exclusions:

(1) Any agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
(2) Non-viable select agent organisms or nonfunctional toxins.
(3) Fixed tissues that bear or contain select agents or toxins.
(4) Genetic elements or sub-units of agents or toxins, if the genetic elements or sub-units are not capable of causing disease.

Appendix D Select Agent Exemption Declaration

Carnegie Mellon University requires all principal investigators in possession of biological agents and/or toxins specified in **Table 1: Select Agent List** of **BS2.2 Select Agent Program** to complete this form. Complete and return the form to the Biosafety Office, 311 Mellon Institute.

By placing an "X" in the box adjacent to each statement, printing your name and signing below you are indicating the following is true and accurate.

☐ I am possession of a select agent listed in **Table 1: Select Agent List** of **BS2.2 Select Agent Program**.

☐ I have registered the select agent in my possession with Carnegie Mellon University via the completion and submission of **BS2.2 form 1, *Select Biological Agent and/or Toxin Registration Application***.

☐ I understand the quantity exemption limit for the toxin(s) in my possession and I agree to never exceed the applicable possession limit without prior approval from the university's Environmental Health and Safety Department and the federal government.

☐ I understand that failure to comply with theses quantity limits for specified toxins will result in a federal violation of the Select Agent regulations, which may have serious consequences including termination and/or criminal penalties.

☐ I agree to abide by the university's BS2.2 Select Agent Program and all accompanying Appendices.

_____

Print Name

_____ _____

Signature Date

Biological Safety Office:

Select Agent Authorization (SA) Number:_____

□ Exempt from the requirements of the regulation. The principal investigator does not, at any time, have any more that the aggregate amounts listed in 42 CFR 73.4 and 42 CFR 73.5 for each agent under the control of a single principal investigator

□ Subject to the requirements of the regulation. The principal investigator has control of aggregate amounts of listed agents that are above the exempted quantities. CDC Registration Number: _____

_____ _____

Biosafety Officer Signature **Date**

12.0 References

(1) Biosafety in Microbiological and Biomedical Laboratories (CDC-NIH) 4th ed.

(2) Block, S., 2001. Disinfection, Sterilization, and Preservation, 5th ed. Lippincott Williams & Wilkins, Philadelphia, PA.

(3) The Merck Index: an encyclopedia of chemicals, drugs, and biologicals, 10th ed. Rahway, New Jersey, Merck and Co. Inc.

(4) Morin, R.S., and Kozlovac, J.P. 2000. Biological Select Agents, p. 261-272. In D.O. Fleming, and D.L. Hunt (ed.), Biological Safety, Principle and Practices. ASM Press, Washington, D.C.

(5) Select Agent Program: Destruction of Select Agents; As provided on University of Pennsylvania's website (October 2003).

(6) Slein, M.W., and Sansone, E.B. 1980. Degradation of Chemical Carcinogens, An Annotated Bibliography. Van Nostrand Reinhold Company, New York, N.Y.