FAU
FLORIDA ATLANTIC UNIVERSITY

Division of Administrative Affairs

Environmental Health and Safety
Policy #MAN07
Select Agent Program Manual

Version #2.0

Effective: 09/23/2021	**Revised: 09/23/2021**

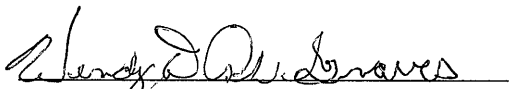
1. PURPOSE:

Cover page for FAU Select Agent Program Manual

2. CONTENTS:

FAU Select Agent Program Manual, 17 pages.

Approved and issued by order of:



Wendy Ash Graves
Director, Environmental Health and Safety

DATE: 09/23/2021

POLICY MAINTENANCE SECTION

Last Revision Date	09/23/2021
Last Revision By	W. Ash Graves
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THIS POLICY RESCINDS ALL OTHER WRITTEN DIRECTIVES REGARDING THIS TOPIC.

3. RECORD OF CHANGES/STATUS CONTROL:

Version	Date	Summary of Changes	Reviewed By
2.0	09/23/2021	Regulatory update	• W. Ash Graves

FLORIDA ATLANTIC UNIVERSITY
ENVIRONMENTAL HEALTH AND SAFETY

Select Agent Program Manual

Florida Atlantic University

Office of Environmental Health and Safety

Version 2

Effective: September 23, 2021

Table of Contents

Introduction

The Federal Select Agent Program, established in response to a Congressional mandate, regulates the possession, use and transfer of biological select agents and toxins that could pose a threat to human, animal and plant health and safety. The Federal Select Agent Program is jointly managed by the Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC) and the US Department of Agriculture (USDA).

This program outlines the requirements for research and clinical facilities that may want to use or possess these select agents and toxins, which are listed in Appendix 1.

Florida Atlantic University (FAU) and all individuals involved with select agents are required to comply with the Select Agent Program. Compliance is required under Federal Law; noncompliance can result in substantial penalties for both an individual and the University. All individuals must register with the University and the Federal government if applicable prior to working with any select agent or toxin.

Program Overview

Florida Atlantic University Department of Environmental Health and Safety has developed this program to conform to the regulatory conditions implemented by the Public Health Security and Bioterriorism Preparedness and 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. Those investigators desiring to utilize a select agent or toxin for research should review the regulations of the Select Agent Program: https://www.selectagents.gov/.

The Select Agent Program includes the following stipulations:

1. The formation of lists by the U.S. Department of Health and Human Services (HHS) and the Animal and Plant Health Inspection Service (APHIS) of biological agents and toxins that have the potential to pose severe threats to the public's health and safety.
2. The regulations by HHS and APHIS established the following: safety measures for select agents including proper training and appropriate skills; appropriate laboratory facilities to contain and dispose of the agents; security of select agents to prevent their use in domestic and international terrorism; procedures to protect the public; and ensure the availability of biological agents and toxins for research, education and other legitimate purposes.
3. The registration of individuals for the possession, use and transfer of select agents including provisions to ensure that persons registering have a lawful purpose to possess, use and transport the agents; and procedures to identify and characterize the agents held at a facility 4. Prompt notification of the release of a select agent outside the biocontainment area.

5. The regulations ensure that appropriate safeguards and security arrangements for persons possessing, using or transferring the agents exist at a facility. Registered persons shall have their names and other identifying information submitted to the Department of Justice (DOJ). Access shall be denied to those identified as restricted persons; access shall be granted to only those individuals identified by the Secretaries of HHS and APHIS and DOJ; the DOJ shall use criminal, immigration, national security and other electronic data bases to determine if a person is a restricted person or otherwise suspected of committing a crime, being involved in an organization that engages in domestic or international terrorism, or being an agent of a foreign power.
6. The establishment of penalties for violation of the Patriot Act.

Federal Regulations, 7 CFR Part 331 and 9 CFR Part 121 "Agricultural Bioterrorism Protection Act of 2002; Possession, Use & Transfer of Biological Agents and Toxins" and "42 CFR Parts 72 and 73 Possession, Use, and Transfer of Select Agents and Toxins" Final Rule published March 18, 2005 mandates that an entity develop and implement a security plan to establish policy and procedures that ensure the security of areas containing select agents and toxins.

The security plan must be based on a systematic evaluation in which threats are defined, vulnerabilities are examined and risks associated with those vulnerabilities are mitigated with a security systems approach.

Responsibilities

Responsible Official (RO)

Each entity must assign a Responsible Official (RO) to oversee the Select Agent Program. The RO responsibilities include the following:

1. Must be approved by the lead federal agency following a security risk assessment by the Attorney General.
2. Must be familiar with all of the requirements of the select agent regulations.
3. Must have the authority and responsibility to act on behalf of the entity.
4. Coordinates all activities involving the registration with federal agencies, intramural or extramural transfers, disposal and exclusion or exemption from federal regulation. The RO submits all applications to the CDC and/or USDA.
5. Must ensure compliance with all requirements of the regulations.
6. Must ensure that annual inspections are conducted for each laboratory where select agents are used. Must document the results of each inspection and identify any deficiencies to be corrected.
7. Must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing.

Alternate Responsible Official (ARO)

The ARO must meet all the qualifications for the RO and must be able to conduct all the activities of the RO in the absence of the RO.

Principal Investigators (PI)

1. Register the select agent project with the RO and get approval from the federal government before working with select agents.
2. Oversee the proper containment laboratory to work with the select agents in accordance with CDC Biosafety in Microbiological and Biomedical Laboratories publication.
3. Develop Standard Operating Procedures and ensure compliance by lab personnel.
4. Maintain a log of select agent stock quantities stored in accordance with regulations.
5. Maintain a use log of select agent and reconciliation.
6. Will report to the Responsible Official or Alternate Responsible Official:
    a) Any loss or compromise of their keys, passwords, combinations.
    b) Any suspicious persons or activities.
    c) Any loss or theft of select agents or toxins.
    d) Any release of select agents or toxins.
    e) Any sign that inventory and use records of select agents or toxins have been altered or otherwise compromised.
7. Allow unescorted access only to federally approved individuals who are performing a specifically authorized function during hours required to perform the defined job.
8. Allow non-approved individuals to conduct routine non-laboratory functions only when escorted and continually monitored by approved individuals or when select agents or toxins are not in use.
9. Will report to the RO/ARO all select agents used and stored in the laboratory.
10. Will notify the RO/ARO of changes requested in the use of select agents or toxins and will wait to make the changes until the lead federal agency has approved them.

Authorized Persons

1. Attend special training from the RO prior to handling select agents

2. Handle select agents safely, secure them properly when not in use, update inventories frequently and dispose of materials appropriately

Policy and Procedures

Determination

Select agents are those infectious agents, biologically-derived toxins and those genetic elements from any select agent containing nucleic acid sequences 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 clinic 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 FAU.
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 September 2021 is found in Appendix 1. Investigators should consult the Select Agent Program website 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.

Select Agent Registration

Principal Investigators interested in working with select agents or toxins must contact the RO, and complete a Select Agent Registration Form (see Appendix 2). In addition, all work with Select Agent material must be approved by the Institutional Biosafety Committee prior to work beginning. This applies to exempt Select Agents as well as those that require federal registration.

If the PI's select agent work falls under the regulations, the PI must register their intent to use Select Agent materials with the CDC and/or APHIS and receive approval prior to bringing Select Agent materials to FAU. The process for registration begins with obtaining access to the Secure Access Management Services through the Federal Select Agent Program Website. The entire registration process is completed online by the PI in coordination with the RO. Registration includes; floor plans of the appropriate containment facility, personnel background checks, biosafety and biosecurity procedures, and emergency response plan. The federal agency will also conduct a facility inspection to ensure compliance with the regulations.

Restricted persons are prohibited from accessing or working with Select Agents. "Restricted Person" means any individual who:

Is under indictment for a crime punishable by imprisonment for a term exceeding one 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 lawfully 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 act of international terrorism; or

Has been discharged from the Armed Services of the United States under dishonorable conditions.

Personnel Security Risk Assessment

An individual may not have access to a select agent or toxin unless that individual has been approved by APSIS/CDC following a risk assessment by the FBI. Once a registration process has begun the DOJ will assign each individual seeking clearance an identifying number. The RO will communicate this number to each person. Those persons will then complete an FD-961 Form and returns the form to the RO for review and signature. Additionally, the RO will request fingerprint packages from the FBI and assist in completing fingerprint profiles for each person. The FD-961 along with two fingerprint packaged per person will be returned to the FBI by the RO.

Physical Security Systems

A risk assessment must be completed based on information and past occurrence of weather, fire or miscellaneous events, the probability of occurrence and severity of impact to protect critical facility assets where select agents are used. A range of security protection for each select agent will be implemented based on site-specific risk assessment and threat analysis.

1. Laboratories shall be locked when unoccupied.
2. Keys or other security devices will be used to permit entry into these areas; the RO will control key distribution.
3. All freezers, refrigerators, cabinets, incubators and other containers where select agents are stored will be locked when they are not in direct view of an approved Select Agent researcher; the Select Agent Principal Investigator will control key distribution.

4. Only approved select agent users will have access to select agents or equipment in which select agents are being used.
5. Unauthorized personnel entering select agent areas must be escorted and monitored by approved personnel.
6. Visitor access to the area where select agents are used or stored must be controlled. A log must be kept with the following information:
    a. The name of each visitor accessing area
    b. Date and time of entry.
    c. The name of the approved personnel escorting the visitor.
7. Access logs will be maintained by the lab personnel and made available to the RO/ARO and other authorized individuals upon request.
8. The RO shall keep an up-to-date list of persons who possess door keys and knowledge of keypad access numbers.
9. Personnel using select agents or toxins must report immediately the following to the RO/ARO.
    a. Any loss or compromise of their keys, ID cards, passwords, combinations.
    b. Any suspicious persons or activities.
    c. Any loss or theft of select agents or toxins.
    d. Any accidental release of select agents or toxins.
    e. Any sign that inventory and use records of select agents or toxins have been altered or otherwise compromised.
10. Non-approved personnel will do routine cleaning, maintenance, and repairs only when escorted and continually monitored by approved individuals while in areas where select agents are in use.
11. Suspicious persons will be immediately reported to the RO and the FAU police.
12. Suspicious packages will be immediately reported to the RO and FAU police.
13. Federal agencies will be notified if the suspicious incident is credible.

Non-regulated Amounts

Certain select agent materials that meet regulatory criteria are exempt from registration with the CDC and/or APHIS. A list of agents and exempt quantities can be found in Appendix 2.

Exclusions

Certain strains of select agents are excluded from the regulations because of their attenuated nature and inability to cause disease. These agents can be found at the Select Agent website. Investigators can apply to the Federal Select Agent Program to have strains of agents declared excluded from the regulations. Details can be found on the Select Agent website.

Training Requirements

Select Agent training, provided by the RO, is required for authorized persons who are allowed access to Select Agents. Lab personnel handling infectious material will be trained in safety compliance for initial training and yearly refresher. The training will include; biosafety regulations, agent specific training, laboratory practices such as engineering controls, decontamination, security measures and incident response procedures.

After the training, the PI will train the workers in the laboratory specific requirements for working with the select agent. The training will be based on Standard Operating Procedures and other practical details will be also taught. The person will not be considered an "authorized personnel" until a procedural drill is carried out. Practical exercises done by the personnel will demonstrate proficiency in laboratory procedures.

Transfer and Shipment

The Federal Select Agents Program has detailed information concerning the transfer of Select Agents/Toxins on their website. Prior to transfer or shipment of select agents, the following procedures must be adhered to:

1. The sender and the recipient must have a certificate of registration from APHIS/CDC that covers the select agent or toxin being transferred or shipped.
2. An APHIS/CDC Form 2 must be completed and submitted to RO/ARO prior to transferring or shipping the agent, if required (see website for further information about if Form 2 is required). The form can be submitted online, by email or by FAX
3. APHIS/CDC must be notified prior to transfer/shipping by completing Form 2 online. They will authorize the transfer/shipment by supplying an approval/authorization number.
4. The shipper must receive confirmation in writing that shipment has been received. A copy of receipt will be sent to the RO/ARO.

5. The RO/ARO of the recipient shall supply a completed paper copy of the Form 2 to the sender and to APHIS/CDC within 2 business days of receipt of the select agent or toxin.
6. The recipient immediately reports to the APHIS/CDC if the select agent or toxin has not been received within 48 hours after the expected delivery time or if the package received containing select agents or toxins has been leaking, missing samples or was otherwise damaged. This report is followed by the submission of a APHIS/CDC Form 3.
7. All shipments must comply with DOT and IATA regulations.

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 plans;
5. Ensure that annual inspections are conducted for all registered areas where select agents or toxins are stored or used in order to determine compliance with regulations;
6. Review, approve and document validated inactivation procedures and viable select agent removal procedures.
7. 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 RO's designee and documented

The PI shall:

1. Maintain current and accurate Select Agent inventory as described in the relevant regulation. There is no specific form for inventory, but PIs should follow the regulations and include the following information:

    - 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.

Destruction

Destruction and disposal of select agents must be done in accordance with federal regulations. Methods of destruction must be validated and confirmed by the RO.

APPENDIX 1

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

HHS Select Agents and Toxins

Abrin
Bacillus cereus Biovar *anthracis*
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus
Francisella tularensis
Lassa fever virus
Lujo virus
Marburg virus
Monkeypox 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)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin

South American Haemorrhagic Fever viruses:

- Chapare
- Guanarito
- Junin
- Machupo
- Sabia

Staphylococcal enterotoxins (subtypes A,B,C,D,E)
T-2 toxin
Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses:

- Far Eastern subtype
- Siberian subtype

Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)
Variola minor virus (Alastrim)
Yersinia pestis

Overlap Select Agents and Toxins

Bacillus anthracis
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei
Burkholderia pseudomallei
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus

USDA Select Agents and Toxins

African horse sickness virus
African swine fever virus
Avian influenza virus
Classical swine fever virus
Foot-and-mouth disease virus
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum
Mycoplasma mycoides
Newcastle disease virus
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus

USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins

Coniothyrium glycines
(formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)
Peronosclerospora philippinensis (Peronosclerospora sacchari)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

APPENDIX 2

SELECT AGENT REGISTRATION FORM

Complete this form if a laboratory facility plans to use the agents/toxins listed below. Please review the following list, check all that apply and return to EH&S. ***Failure to report information on this form could result in a fine up to $250,000 for an individual or $500,000 for a facility or imprisonment up to five years or both for each violation***.

Name of Faculty Member/Lab Manager: _____

Cellular Phone: _____ Department: _____

Lab Location: _____ E-mail: _____

Select Agents	Quantity Planning to Use
HHS AGENTS	
Abrin	
Bacillus cereus Biovar anthracis	
Botulinum neurotoxins	
Botulinum neurotoxin producing species of Clostridium	
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)	
Coxiella burnetii	
Crimean-Congo haemorrhagic fever virus	
Diacetoxyscirpenol	
Eastern Equine Encephalitis virus	
Ebola virus	
Francisella tularensis	
Lassa fever virus	
Lujo virus	
Marburg virus	
Monkeypox 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)	
Ricin	

Select Agents	Quantity Planning to Use
Rickettsia prowazekii	
SARS-associated coronavirus (SARS-CoV)	
Saxitoxin	
Abrin	
Bacillus cereus Biovar anthracis	
Botulinum neurotoxins	
Botulinum neurotoxin producing species of Clostridium	
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)	
Coxiella burnetii	
Crimean-Congo haemorrhagic fever virus	
Diacetoxyscirpenol	
Eastern Equine Encephalitis virus	
Ebola virus	
Francisella tularensis	
Lassa fever virus	
Lujo virus	
Marburg virus	
Monkeypox 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)	
Ricin	
Rickettsia prowazekii	
SARS-associated coronavirus (SARS-CoV)	
Saxitoxin	
South American Haemorrhagic Fever viruses:	
Chapare	
Guanarito	
Junin	
Machupo	
Sabia	
Staphylococcal enterotoxins (subtypes A,B,C,D,E)	
T-2 toxin	
Tetrodotoxin	

Select Agents	Quantity Planning to Use
Tick-borne encephalitis complex (flavi) viruses:	
Far Eastern subtype	
Siberian subtype	
Kyasanur Forest disease virus	
Omsk hemorrhagic fever virus	
Variola major virus (Smallpox virus)	
Variola minor virus (Alastrim)	
Yersinia pestis	
Overlap Select Agents and Toxins	
Bacillus anthracis	
Bacillus anthracis Pasteur strain	
Brucella abortus	
Brucella melitensis	
Brucella suis	
Burkholderia mallei	
Burkholderia pseudomallei	
Hendra virus	
Nipah virus	
Rift Valley fever virus	
Venezuelan equine encephalitis virus	
USDA Select Agents and Toxins	
African horse sickness virus	
African swine fever virus	
Avian influenza virus	
Classical swine fever virus	
Foot-and-mouth disease virus	
Goat pox virus	
Lumpy skin disease virus	
Mycoplasma capricolum	
Mycoplasma mycoides	
Newcastle disease virus	
Peste des petits ruminants virus	
Rinderpest virus	

Select Agents	Quantity Planning to Use
Sheep pox virus	
Swine vesicular disease virus	
USDA Plant Protection and Quarantine (PPQ)	
Select Agents and Toxins	
Coniothyrium glycines	
(formerly Phoma glycinicola and Pyrenochaeta glycines)	
Peronosclerospora philippinensis	
(Peronosclerospora sacchari)	
Ralstonia solanacearum	
Rathayibacter toxicus	
Sclerophthora rayssiae	
Synchytrium endobioticum	
Xanthomonas oryzae	

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

☐ Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed above, or their toxic subunits. _____

Explain type of work that will be performed with the agents or toxins checked above:

Requirements for Access (e.g., key, key card, push button code, other): _____

As PI, I ***do not*** at any time ***have more*** than the following aggregate amounts of select agents (in the purified form or in combinations of pure and impure forms) under my control: _____

The information above accurately indicates my research use of the Select Agent(s) in my laboratory(s). I will comply with all applicable laws pertaining to select agent use.

_____

Signature: Principal Investigator **Date**

E-mail completed form to Biological Safety Officer – bso@fau.edu

APPENDIX 3

List of Permissible Select Agent Toxin Amounts

Toxin	Maximum Amount Permitted
Abrin	1000 mg
Botulinum neurotoxins	1 mg
Short, paralytic alpha conotoxins	100 mg
Dacetoxyscirpenol (DAS)	10,000 mg
Ricin	1000 mg
Saxitoxin	500 mg
Staphylococcyl Enterotoxins (Subtypes A, B, C, D, and E)	100 mg
T-2 toxin	10,000 mg
Tetrodotoxin	500 mg