Select Agent Program

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Introduction

This program outlines the requirements for research and clinical facilities that may want to use or possess certain biological materials known as select agents. Select Agents are specifically regulated pathogens and toxins that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products (see Appendix A). These agents could be used in acts of bioterrorism on human, plant or animal populations. These agents are regulated by the Department of Health and Human Services, the U.S. Department of Agriculture, and the Department of Homeland Security.

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; non-compliance 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

There are a number of rules and regulations that govern the use of select agents. The Antiterrorism and Effective Death Penalty Act of 1996 and the USA Patriot Act of 2002 established criminal penalties for possession of certain biological agents and toxins if used as a weapon or for any reason not reasonably justified for prophylactic, protective, bona fide research or other peaceful purposes. In addition, the Acts established certain controls over select agents to ensure that no "restricted person" transports, ships or possesses select agents.

The Public Health Security and Bioterriorism Preparedness and Response Act of 2002 greatly expanded the control of possession, transport and use of select agents that includes the following.

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 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.

Exclusions and Exemptions

There are some select agents or toxins that are excluded from the regulations, however, they will still need to be approved for their use at Florida Atlantic University through the Institutional Biosafety Committee and verified that the exclusion or exemption is applicable. The following are excluded from complying with the regulations:

- Those agents or toxins that are in their naturally occurring environment, provided that it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Non-viable select agent organisms or non-functional toxins.
- Certain attenuated and vaccine strains of select agents and toxins. Please check the following link for the Notification of Excluded Attenuated Strains**.** However, an individual or entity that possesses, uses, or transfers an excluded attenuated strain will be subject to the regulations if there is any reintroduction of factor(s) associated with virulence or other manipulations that modify the attenuation such that virulence is restored or enhanced.
- Certain toxins, under the control of an investigator, if the aggregate amount does not at any time exceed the following:

HHS Toxins [§73.3(d)(3)]	***Amount***
Abrin	100 mg
Botulinum neurotoxins	0.5 mg
Conotoxin ($X_1CCX_2PAGGX_3X_4X_5X_6CX_7$)	100 mg
Diacetoxyscirpenol (DAS)	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Staphylococcal enterotoxins	5 mg
T-2 toxin	1000 mg
Tetrodotoxin	100 mg

The toxin quantities listed above are referred to as "Exempt" quantities and toxins whose

aggregate amount exceeds these amounts at any time must comply with the federal regulations and be approved by the federal government.

An entity may apply for an exemption from the requirements of 7 CFR 331, 9 CFR 121, or 42 CFR 73 in order to: (a) use an investigational product that is, bears, or contains Select Agents or toxins, or, (b) provide a response to a public health or agricultural emergency. This exemption request (APHIS/CDC Form 5) must be sent to either APHIS or CDC for consideration. The Biosafety Officer will apply for an exemption for each Principal Investigator requesting this exemption.

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. Must ensure compliance with all requirements of the regulations.
5. 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.
6. 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/NIH 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.

Policy and Procedures

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 B). In addition, all work with Select Agent material must be approved by the Institutional Biosafety Committee. 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 PI in coordination with the RO will complete the application packet and the RO will submit the completed application to the appropriate federal agency. 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 Attorney General. Each individual seeking clearance must complete a Bioterrorism Preparedness and Response Act FBI Information form and submit fingerprints to the FBI. The RO will coordinate this procedure.

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.

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

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.
3. APHIS/CDC must be notified prior to transfer/shipping by faxing them a completed Form 2. 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.
7. All shipments must comply with DOT and IATA regulations.

Records

1. The RO must keep an up-to-date accurate list of all individuals approved for Select Agent access.
2. The RO must maintain records pertaining to inspections; safety, security and emergency response plans; training; transfer documents and incidents reports.
3. Principal investigators must maintain a current and accurate select agent inventory as described in the regulations.
4. All records must be kept for a minimum of 3 years.

APPENDIX A

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

HHS SELECT AGENTS

ABRIN
BOTULINUM NEURTOXINS
CLOSTRIDIUM BOTULINUM
CONOTOXINS ($X_1CCX_2PAGGX_3X_4X_5X_6CX_7$)
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 1918 INFLUEZENA VIRUS
RICIN
RICKETTSIA PROWAEKII
SARS-COV
SAXITOXIN
SOUTH AMERICAN HAEMORRHAGIC FEVER VIRUSES
STAPHYLOCOCCAL ENTEROTOXINS
T-2 TOXIN
TETRODOTOXIN
TICKBORNE ENCEPHALITIS COMPLEX (FLAVI) VIRUSES
VARIOLA MAJOR VIRUS (SMALLPOX)
VARIOLA MINOR VIRUS (ALASTRIM)
YERSINIA PESTIS

USDA-HHS OVERLAP SELECT AGENTS

BACILLUS ANTHRACIS
BRUCELLA ABORTUS
VENEZUELAN EQUINE ENCEPHALITIS VIRUS
BRUCELLA MELITENSIS
BRUCELLA SUIS
BURKHOLDERIA (PSEUDOMONAS) MALLEI
BURKHOLDERIA (PSEUDOMONAS) PSEUDOMALLEI
HENDRA VIRUS
NIPAH VIRUS
RIFT VALLEY FEVER VIRUS

USDA SELECT AGENTS

AFRICAN HORSE SICKNESS VIRUS
AFRICAN SWINE FEVER VIRUS
AVIAN INFLUENZA VIRUS (HIGHLY PATHOGENIC)
CLASSICAL SWINE FEVER VIRUS
FOOT AND MOUTH DISEASE VIRUS
GOAT POX VIRUS
LUMPY SKIN DISEASE VIRUS
MYCOPLASMA MYCOIDES SUBSPECIES MYCOIDES
NEW CASTLE DISEASE VIRUS
PESTE DES PETITS RUMINANTS
RINDERPEST VIRUS
SHEEP POX VIRUS
SWINE VESICULAR DISEASE VIRUS

USDA PLANT SELECT AGENTS

PERONOSCLEROSPORA PHILIPPINENSIS
PHOMA GLYCINICOLA
RALSTONIA SOLANACEARUM
RATHAYIBACTER TOXICUS
SCLEROPHTHORA RAYSSIAE VAR ZEAE
SYNCHYTRIUM ENDOBIOTICUM
XANTHOMONAS ORYZAE

APPENDIX B

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:

_____ Phone: _____

Department: _____ Lab Location:

_____E-mail: _____

HHS SELECT AGENTS	QUANTITY PLANNING TO USE
☐ ABRIN	_____
☐ BOTULINUM NEURTOXINS	_____
☐ CLOSTRIDIUM BOTULINUM	_____
☐ CONOTOXINS ($X_1CCX_2PAGGX_3X_4X_5X_6CX_7$)	_____
☐ 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 1918 INFLUEZENA VIRUS	_____
☐ RICIN	_____
☐ RICKETTSIA PROWAEKII	_____
☐ SARS-CoV	_____
☐ SAXITOXIN	_____
☐ SOUTH AMERICAN HAEMORRHAGIC FEVER VIRUSES	_____
☐ STAPHYLOCOCCAL ENTEROTOXINS	_____
☐ T-2 TOXIN	_____
☐ TETRODOTOXIN	_____
☐ TICKBORNE ENCEPHALITIS COMPLEX (FLAVI) VIRUSES	_____
☐ VARIOLA MAJOR VIRUS (SMALLPOX)	_____
☐ VARIOLA MINOR VIRUS (ALASTRIM)	_____
☐ *YERSINIA PESTIS*	_____

USDA-HHS OVERLAP SELECT AGENTS	QUANTITY PLANNING TO USE
☐ *BACILLUS ANTHRACIS*	_____
☐ *BRUCELLA ABORTUS*	_____
☐ *BRUCELLA MELITENSIS*	_____
☐ *BRUCELLA SUIS*	_____
☐ *BURKHOLDERIA (PSEUDOMONAS) MALLEI*	_____
☐ *BURKHOLDERIA (PSEUDOMONAS) PSEUDOMALLEI*	_____
☐ *HENDRA VIRUS*	_____
☐ *NIPAH VIRUS*	_____
☐ RIFT VALLEY FEVER VIRUS	_____
☐ VENEZUELAN EQUINE ENCEPHALITIS VIRUS	_____

Part 2
SELECT AGENT REGISTRATION FORM

USDA SELECT AGENTS	QUANTITY PLANNING TO USE
☐ AFRICAN HORSE SICKNESS VIRUS	_____
☐ AFRICAN SWINE FEVER VIRUS	_____
☐ AVIAN INFLUENZA VIRUS (HIGHLY PATHOGENIC)	_____
☐ CLASSICAL SWINE FEVER VIRUS	_____
☐ FOOT AND MOUTH DISEASE VIRUS	_____
☐ GOAT POX VIRUS	_____
☐ LUMPY SKIN DISEASE VIRUS	_____
☐ *MYCOPLASMA CAPRICOLUM*	_____
☐ *MYCOPLASMA MYCOIDES*	_____
☐ NEW CASTLE DISEASE VIRUS	_____
☐ PESTE DES PETITS RUMINANTS	_____
☐ SHEEP POX VIRUS	_____
☐ SWINE VESICULAR DISEASE VIRUS	_____

USDA PLANT SELECT AGENTS	QUANTITY PLANNING TO USE
☐ *PERONOSCLEROSPORA PHILIPPINENSIS*	_____
☐ *PHOMA GLYCINICOLA*	_____
☐ *RALSTONIA SOLANACEARUM*	_____
☐ *RATHAYIBACTER TOXICUS*	_____
☐ *SCLEROPHTHORA RAYSSIAE VAR ZEAE*	_____
☐ *SYNCHYTRIUM ENDOBIOTICUM*	_____
☐ *XANTHOMONAS ORYZAE*	_____
☐ *XYLELLA FASTIDIOSA* (CITRUS VARIEGATED CHLOROSIS STRAIN)	_____

☐ 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**

Send completed form to FAU EH&S 112 Campus Operations Building Boca Raton, FL 33431