

# Florida International University

## Guidelines for Select Agent and Toxin Use

**DEPARTMENT OF RISK MANAGEMENT &  
ENVIRONMENTAL HEALTH & SAFETY**

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*An ounce of prevention is worth far more than a pound of cure*

This document outlines the methods by which EH&S will implement procedures for receipt, handling, storage, delivery, use, transfer, and disposal of Select Agents/Toxins, as mandated by the Select Agent Rule 42 CFR 73, 9 CFR 121, and 7 CFR 331.

Last date revised: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Approved by: **William Youngblut**                      **Assistant Director**  
(Department Head or Unit Supervisor)                      (Title)

The University Responsible Official is responsible for assuring **all** Authorized Users fulfill the compliance requirements of the Select Agent Rule. The following individual is designated to fulfill this responsibility:

**Tamece Knowles, Biosafety Officer**    **348-3387**  
Employees name or title    Telephone #

**PURPOSE**

The purpose of this manual is to provide information to ensure that all federally regulated **Select Agents** on Florida International University campuses are handled safely, secured properly, and registered with the Department of Health and Human Services (HHS), **Centers for Disease Control and Prevention (CDC)** and/or the United States Department of Agriculture, **Animal Plant Health Inspection Service (APHIS)**.

**APPLICABILITY**

These guidelines apply to University personnel who receive, possess, use, transfer, acquire, or dispose of Select Agents/Toxins on University grounds.

The Select Agent and Toxin Use Guidelines are based upon the guidelines of:

The Center for Disease Control and Animal and Plant Health Inspection Agency  
Public Health Service, Department of Health and Human Services  
42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121  
Revised April 18, 2005

**Access:** the freedom or ability to obtain or make use of Select Agents or locations on University premises where Select Agents and Toxins are used and/or stored.

**Authorized person:** an individual who has been approved for access to Select Agents through the successful completion of an FBI security risk assessment (Section 6.6) and all University approval procedures.

**Authorized User:** A User (see below) who has authorization from the University to purchase, handle, store, transfer or dispose of Special Hazard Materials

**Biological agent:** 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.

**Biosecurity:** protection of select agents and toxins, or critical relevant information against theft or diversion by those who intend to pursue intentional misuse.

**Entity:** 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 Florida International University.

**Public Health Security and Bioterrorism Preparedness and Response Act of 2002:** requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies; necessitates that individuals possessing, using or transferring agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (9 CFR 121 and 7 CFR 331). Public Law 108-188 June 12, 2002.

**Responsible Official:** the individual designated by the entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations. For purposes of this policy, the RO is the Associate VP of Environmental Health and Safety.

**Restricted Person:** any individual who:

- A. is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
- B. has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

- C. is a fugitive from justice;
- D. is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));
- E. is an alien illegally or unlawfully in the United States;
- F. has been adjudicated as a mental defective or has been committed to any mental institution;
- G. is an alien (other than an alien lawfully admitted for permanent residence) who is a national of any 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; or has been discharged from the Armed Services of the United States under dishonorable conditions.

**Risk:** a measure of the potential loss of a specific biologic agent of concern, on the basis of the probability of occurrence of an adversary event, effectiveness of protection, and consequence of loss.

**Select Agent:** biological agents or toxins deemed a threat to the public, animal or plant health, or to animal or plant products by CDC and/or APHIS.

**Special Hazard Materials:** These materials include, but are not limited to, radioactive materials, Drug Enforcement Administration (DEA) controlled substances, select agents, carcinogenic and explosive materials, infectious materials, and laser devices, and any other hazardous materials, the purchase, handling, storage or transfer and disposal of which is regulated by federal, state, or local laws.

**Toxin:** 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/synthesized molecule, whatever their origin and method of production. 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.

**USA PATRIOT ACT of 2001:** a statute enacted by the United States Government in 2001 to deter and punish terrorist acts in the United States and around the world, to enhance law enforcement investigatory tools, and for other purposes.

**User:** Consumer, registrant, permit holder, principal investigator, laboratory manager or laboratory worker designated control of a laboratory space, device, agent, material or specimen.

**APHIS:** Animal Plant and Health Inspection Services

**ARO:** Alternate Responsible Official

**AU:** Authorized User

**CDC:** Centers for Disease Control

**EH&S:** Environmental Health and Safety

**HHS:** Health and Human Services

**IBC:** Institutional Biosafety Committee

**NIAID:** National Institute of Allergy and Infectious Diseases

**NIH:** National Institute of Health

**RO:** Responsible Official

**USDA:** United States Department of Agriculture

### **Vice President of Research**

The Vice President of Research is the responsible corporate officer and provides oversight for the various regulatory committees or offices involved with the Select Agent program. All select agent registration forms are approved signed by the Vice President.

### **Responsible Official**

The Associate VP of Environmental Health and Safety is the Responsible Official (RO) for Florida International University. All activities involving registration with federal agencies, intramural or extramural transfers, disposal and exclusion or exemption from regulation must be coordinated through EH&S and reviewed and approved by the RO. The RO submits all applications to CDC and/or USDA.

### **Alternate Responsible Official**

The Biosafety Officer is the Alternate RO (ARO) for Florida International University. 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. The responsibilities of the ARO also include the following:

- Develop and implement safety, security and emergency response plans
- Allow only approved individuals to have access to select agents or toxins
- Provide appropriate training for safety, security and emergency response
- Assure that transfer of select agents or toxins is done according to the rules of the Select Agent Rule
- Provide timely notice of any theft, loss or release of a select agent or toxin
- Maintain detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins
- Report the identification of a select agent or toxin as a result of clinical diagnosis, verification or proficiency testing
- Conduct regular inspections, at least annually, of the laboratory where select agents or toxins are stored or used to ensure compliance with all procedures and protocols of the safety plan. The results of these inspections must be documented and any deficiencies must be corrected.

### **Institutional Biosafety Committee**

The IBC is advisory to the RO on all matters regarding the safe use recombinant DNA in accordance with NIH specifications. It is the IBC's responsibility to monitor research activities that fall under applicable regulations. Any use of recombinant DNA must be reviewed and approved by the IBC *prior* to the initiation of experiments.

Tasks of the IBC include the following:

- initiate the registration of biohazard and recombinant DNA research by providing department chairs with the registration materials
- review and approve research proposals involving recombinant DNA and biohazards and approve those that comply with NIH and CDC guidelines and university policy

- adopt policies supporting the safe use of biohazards and the elimination or reduction of exposure to biohazards
- address biosafety issues related to experimentally infected laboratory animals.

### **Authorized User**

The Authorized User (AU) is responsible to direct projects or programs involving Select Agents in compliance with all regulatory requirements. The AU is responsible for the following:

- Complying with the University policy on purchase, use, storage, transfer and disposal of special hazard materials
- Reporting to the ARO all select agents and toxins used and/stored
- Notifying the ARO of all authorized personnel with access to select agents and toxins
- Allowing unescorted access only to approved individuals who are performing a specifically authorized function during hours required to perform the defined job.
- Allowing individuals to conduct routine non-laboratory functions only when escorted and continually monitored by approved individuals
- Maintaining a log of select agent stock quantities stored – select agent identification; storage location; amount stored; date; initial of person doing entry.
- Maintaining a use log of select agent and reconciliation – amount used; date, initials of user.
- Reporting to the Alternate Responsible Official:
  - Any loss or compromise of their keys, passwords, combinations
  - Any suspicious persons or activities
  - Any loss of theft of select agents or toxins
  - Any release of select agents or toxins
  - Any sign that inventory and use records of select agents or toxins have been altered or otherwise compromised.

### **Authorized Persons**

Authorized persons with access to Select Agents and Toxins may include university faculty/staff and students. Authorized persons are required to attend special training prior to handling Select Agents and Toxins and follow prescribed work practices. Authorized persons must handle Select Agents and Toxins safely, secure them properly when they are not in use, update inventories regularly and dispose of materials appropriately when work is completed.

### **Restricted Persons**

Restricted persons are prohibited from obtaining, accessing, or making use of Select Agents and Toxins

### **Public Safety Department**

The Public Safety Department is an integral part of the development and establishment of the FIU security plan. The responsibilities of the PSD shall include the following:

- Act as the point of contact for all law enforcement agencies and investigations.

## **RESPONSIBILITIES**

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- Provide University crime statistics at least twice per year for risk assessments.
- Provide notification to Biosafety Officer of security breaches, thefts, losses, etc in any designated areas. (identified by the Biosafety Officer)
- Provide security for identifying, handling, and inspecting suspicious packages.
- Ensure the Public Safety Officers who will have access to designated areas complete annual awareness training.

### **Human Resources**

Human Resources are responsible for obtaining and maintaining information on "restricted persons" as they pertain to access to select agents.

### **RISK GROUPS**

Risk group classifications are primarily used in the research environment as part of the comprehensive Biosafety risk assessment. Biological agents are classified into four Risk Groups on the basis of the following characteristics:

- *Risk Group 1 (RG1)*: agents are **not** associated with disease in **healthy** human adults
- *Risk Group 2 (RG2)*: agents are associated with human diseases that are rarely serious and for which preventative or therapeutic interventions are often available.
- *Risk Group 3 (RG3)*: agents are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available.
- *Risk Group 4 (RG4)*: agents are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are not usually available.

Risk group classifications correspond to the Biosafety levels (BSL 1-4) described in the FIU Biosafety manual (p.13) and should be performed in collaboration with the Biosafety Officer and the Institutional Biosafety Committee to ensure personnel safety and compliance with established regulations and guidelines.

### **PRIORITY CATEGORIES**

Priority levels were assigned by CDC and NIAID to some select agents and other infectious agents based on the criteria listed below. Although the agents assigned to category A, B, and C are the same for both the CDC and NIAID, the NIAID also took into account the potential for the agent to be weaponized, the lack of a safe and effective vaccine, and the lack of specific diagnostic tests and/or effective treatments in assigning a priority category to agents.

- **Category A** - Highest Priority. This is based on the threat to public safety and the potential for use as weapons for bioterrorism. These agents can be easily disseminated or transmitted from person to person; result in high mortality rates and have the potential for major public health impact; may cause public panic and social disruption; and require special action for public health preparedness.
- **Category B** - Second Highest Priority- These agents are moderately easy to disseminate; result in moderate morbidity rates and low mortality rates; and require specific enhancement of diagnostic capacity and enhanced disease surveillance.
- **Category C** - Third Highest Priority- These agents include emerging pathogens that could be engineered for mass dissemination in the future because of availability; ease of production and dissemination; and potential for high morbidity and mortality rates and major health impact.

### **REGISTRATION**

AUs who fall under the Select Agent and Toxin regulations must register with the CDC/APHIS **PRIOR** to bringing the material to university premises. EH&S will coordinate the federal registration with the CDC Select Agent Program for those AUs requiring registration. Authorized users must complete the application packet (includes SARF and toxin declaration form) and submit it to the RO for submission to CDC/APHIS.

All AUs at FIU in possession of select agents must be registered with the Department of Environmental Health and Safety. AUs considering work with any select agent material must complete **Section A of the Biohazardous Materials Registration Form** and submit it to the RO. **This applies to exempt agents as well as those that require federal registration.**

#### **Note:**

Under the Regulations, certain select agents/toxins that meet the criteria are exempt from registration with the CDC and/or APHIS. Exemptions and exclusions include the following:

- The medical use of toxins for patient treatment is exempt.
- The following select agent toxins are exempt if the aggregate amount under the control of one authorized user does not, at any time, exceed:
  - 0.5 mg of Botulinum neurotoxins
  - 5 mg of Staphylococcal enterotoxins
  - 100 mg of abrin, Clostridium perfringens epsilon toxin, conotoxin, ricin, saxitoxin, shigatoxin, shiga-like ribosome inactivating protein, and tetrodotoxin
  - 1,000 mg of diacetoxyscirpenol and T-2 toxin
- The following select agent organisms or toxins are also exempt:
  - 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.
  - Non-viable select agent organisms or nonfunctional toxins.
  - The vaccine strains of Junin virus (Candid #1), Rift Valley fever virus (MP-12), Venezuelan Equine encephalitis virus vaccine strain TC-83.

To ensure regulatory compliance, authorized users in possession of any of the exempted or excluded select materials are still **required** to register with EH&S.

All authorized users in possession of any of the exempted toxins must sign and date the **FIU Toxin Declaration Form**. AUs are required to maintain an inventory logbook to document quantities, use, and destruction of exempt select agent toxins and materials.

Registration lasts for three years, and will need to be renewed for any AU who wishes to continue working with select agents. Even if the AU is no longer working with the select agent, but still possesses it, the registration must be renewed.

### **TRAINING**

All personnel ordering, possessing, using, transferring, or receiving select agents must have training regarding:

- (1) proper use of engineering, administrative and work practice controls
- (2) personal protective equipment, and security requirements for select agent possession and use
- (3) the symptoms of exposure
- (4) a post-exposure management protocol
- (5) spill cleanup and decontamination,

Select Agent training, provided by EH&S either online or in person, is required for authorized persons who are allowed access to Select Agents.

### **SECURITY**

Security for select agents and toxins should be addressed on several levels. The University and the investigator will work together to evaluate and ensure both physical security and information security. The security plan should be risk-based.

Risk management principles are based on acknowledgement that 1) although risk usually cannot be eliminated, it can be reduced by enhancing protection from validated and credible threats; 2) although threats are possible, certain threats are more probable than others; and 3) all assets are not equally critical. Therefore each facility should implement certain measures to enhance security regarding select agents.

Each facility should develop security policies based on a risk assessment and threat analysis of its assets and select agents. The risk assessment should include a systematic approach in which threats are defined and vulnerabilities examined. The security plan must include collaborations with senior management, scientific staff, human resource officials, information technology (IT) staff, engineering officials, and security officials. This coordination will ensure that security recommendations provide adequate and reasonable laboratory security without impacting the scientific work.

#### **General Facility**

- The investigator must control and document access to *containers* where select agents are stored.
- The investigator must control and document access to the *area* where select agents are stored or used.
- Sharing by an approved individual with any other person of keycards, passwords, codes, or any other unique means of securing select agents or toxins is prohibited.
- Areas where select agents and toxins are stored or used must be separated from public areas of the building.
- Select agents and toxins must not be abandoned. When use is terminated, they must be transferred to another registered individual or entity in accordance with the transfer

requirements, or destroyed by an appropriate process in accordance with the destruction requirements

### **Access Control**

Based on the risk assessment, the following precautions are required for select agent laboratories and recommended for other laboratories using biological agents or toxins:

- A graded level of security protection will be implemented based on site-specific risk and threat analysis
- Laboratories must be locked when unoccupied
- Keys or other security devices will be used to permit entry into these areas; key distribution must be controlled
- Lock all freezers, refrigerators, cabinets, incubators and other containers where select agents are stored when they are not in direct view of a laboratory worker
- Only authorized personnel will have access to select agents
- Unauthorized personnel entering select agent areas must be escorted and monitored by authorized personnel
- Visitor access to the area where select agents are used or stored must be controlled. A log will be kept with the following information:
  - The name of each visitor accessing area
  - Date and time of entry
  - Date and time of leaving
  - Access logs will be maintained by the lab personnel and made available to the RO, ARO, and other authorized individuals.
  - An up-to-date list of persons who possess door keys and knowledge of keypad access numbers or the security system.
- Personnel using select agents or toxins must report immediately the following to the ARO:
  - Any loss or compromise of their keys, passwords, combinations
  - Any suspicious persons or activities
  - Any loss or theft of select agents or toxins
  - Any release of select agents or toxins
  - Any sign that inventory and use records of select agents or toxins have been altered or otherwise compromised.
- Routine cleaning, maintenance, repairs will only be done only when escorted and can be continually monitored by approved individuals.

### **Personnel (Risk Assessment)**

Honest, reliable, and conscientious workers represent the foundation of an effective security plan. The following guidelines should be used when establishing Security-related policies for all personnel:

- Facility administrators and laboratory directors should be familiar with all laboratory workers

- Screening policies should be established for employees who require access to select agent areas (including part- and full-time employees, contractors, emergency personnel, and visitors)
- Ensure that all workers approved for access to select agents wear visible identification badges that include, at a minimum, a photograph, the wearer's name, and an expiration date.

Prior to working with or having access to Select Agents all individuals must undergo a security risk assessment (including fingerprinting) by the FBI. The proper forms and procedures can be obtained via the CDC website ([www.cdc.gov/od/sap/faq.htm#7](http://www.cdc.gov/od/sap/faq.htm#7)).

### **Cyber (Information Technology)**

Security plan policies should address concerns associated with access, use, storage, and transfer of sensitive electronic data. If sensitive electronic data are present, IT specialist should do the following:

- Assess the security of the hardware and software products in addition to the security of the local area networks
- Review IT policies at least annually for consistency and applicability.
- Secure access to the electronic data pertaining to types and locations of select agents used in a laboratory from unauthorized removal.

### **Review and Maintenance of Security Plan**

Security plans should receive periodic performance testing to determine their effectiveness. Test procedures can vary from a simple check of keys, locks, and alarms to a full-scale laboratory or facility exercise.

Safety, security, and IT policies and procedures should be reviewed at least annually for consistency and applicability. These procedures should also be reviewed after any incident or change in regulations. Necessary changes should be incorporated into the revised plans and communicated to all. The following provides time-dependent responsibilities of the authorized user and EH&S during the maintenance and review of the security plan:

#### *Monthly*

Principal investigator shall verify that the physical inventory matches paper inventory

#### *Quarterly*

EH&S shall audit labs to:

- Review lab access logs to verify they are kept up to date
- Verify that work is being done as indicated on the University's federal Certificate of Registration on file with the CDC

- Review safety/security protocols and implementation
- Collect inventory forms

### *Annually*

- Change access codes
- Coordinate exercises with EH&S to evaluate the effectiveness of security, Biosafety, and incidence response plans.
- Review and update security, biosafety, and incidence response plans with EH&S
- Complete select agent update training for all individuals with authorized access. Keep all training records for three years.

### *Continuously*

- Notify EH&S whenever there is a change in lab workers and/or when access codes or keys have been changed
- Follow pertinent lab practices in the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories
- Follow all procedures as outlined in the University's Guidelines for Securing
- Maintain up-to-date standard operating procedures (SOPs). SOPs should include: potential exposure hazards during sample preparation and experimental manipulations (e.g. aerosol generation when transferring, mixing, or centrifuging; use of sharps; excretion by animals; etc.), safety procedures that will be employed to minimize risk (e.g. protective clothing, use of biological safety cabinet, sharps disposal procedures, waste disposal procedures, etc.), proper material disposal techniques, and accidental spill/exposure procedures.
- Maintain up-to-date inventory and access logs.

**AUTHORIZATION**

**Authorized User Application**

All individuals who wish to use select agents/toxins in any type of research must obtain authorization from the Responsible Official **PRIOR** to use. The individual must complete and submit the application packet to the RO. A complete application packet contains:

1. Copies of current resume showing training and experience with select agent and biohazardous materials
2. Copies of select agent training records
3. Contact information including telephone, fax, mailing address and email
4. Project proposal that includes at minimum the following information:
  - a. Select agent to be used
  - b. Quantity to be used (if applicable)
  - c. Location where select agents/toxins will be used (including detailed floor plan)
  - d. Detailed procedure specifying exact use of select agents/toxins
  - e. Detailed safety procedures
  - f. Acknowledgement of receipt and review of the Select agent Guidelines Manual

The completed application will be reviewed by the ARO and the applicant will be notified when it has been approved

**New Proposal/New Work Location Review**

Authorized users that wish to start a new project and/or work at a different location must submit a proposal for the new project with the information listed above under item 4. The new proposal will have to be approved by the ARO, and the applicant will be notified of approved authorization for use of the listed select agent.

**Note:** AUs must be approved for **EACH** select agent/toxin to be used in a proposal.

**ORDERING**

AUs must receive approval to order select agents (including exempt). The following procedures must be followed when ordering select agents:

- All requisitions for must clearly show the type and amount of select agent being ordered, and be submitted to the ARO for approval before being sent to the Purchasing Department. Requests for approval may be faxed (348-3574) or emailed (biosafe@fiu.edu). The investigator will be notified of the approval via e-mail/fax.
- All select agent material must be delivered to the Department of Environmental Health & Safety for logging and record keeping. The delivery address is:

11200 SW 8<sup>th</sup> Street, CSC 162  
Miami, FL 33199.

Copies of the requisition, purchase order and packaging slip will be retained by EH&S. The AU will be notified of the arrival of the shipment.

**NOTE:** In the event that the ARO is unavailable and an emergency purchase is required, the RO or his/her designee is authorized to perform this responsibility.

- After the initial approval, no forms or other documentation are required for repeat orders.

Individuals requesting initial usage, unusual usage, or large quantities of select agent materials may be requested to meet with the ARO to discuss the request and the inspection of the facilities to be used.

### **SHIPPING AND RECEIVING**

All select agents/toxins must be shipped to the Environmental Health and Safety Office *prior* to delivery to the laboratories. This is to ensure proper shipment, notification, and tracking of packages. AUs requiring shipment of select agents/toxins must notify the ARO *prior* to shipment of select agents. Please contact the ARO at 348-3387 for signature on the CDC EA-101 Shipping Form (Appendix A).

Shipper responsibilities include:

- Notifying the ARO of any transportation incident involving a select agent.
- Labeling packages as “Infectious Substances,” or “Infectious Substance and Etiologic Agent”
- Ensuring that the shipper’s name and phone number appear on the outer package, in order to be used in emergencies.
- Assuring that the phone number provided will be answered 24 hours a day by the shipper in case of emergency.
- Obtaining an import permit from the CDC *prior* to importing select agents.
- For questions regarding shipping or permitting issues please contact the ARO at 348-3387/348-2621.

### **TRANSFERS**

Before a select agent is transferred, both the sender and the recipient facilities must be registered with the CDC or APHIS. The agency contacted by the RO is determined by the type of select agent/toxin involved in the transfer. For HHS agents, the RO should contact CDC. For USDA (animal) agents or plant agents/toxins, the RO should contact APHIS. For HHS/USDA overlap agents, the RO should contact either APHIS or CDC.

The recipient of the select agents must complete blocks 1 and 2 of the CDC EA-101 form and submit this form to the RO of the sender. The RO must fax the form to CDC to verify that the requesting facility:

- has a valid, current registration for the select agent being requested,

- that the person requesting the select agent to be transferred is an employee of the requesting facility and has clearance by the Department of Justice as an authorized individual to receive the select agent material, and
- the proposed use of the agent by the recipient is correctly indicated on CDC form EA-101.

Transfer of select agents may not occur without prior approval by the RO. Extramural transfers must receive prior authorization from the ROs at the facilities of the transferor and the recipient. Intramural transfers must be approved by the RO before the transfer occurs.

### **SHIPPING**

Shipping must conform to applicable regulations. Prior to shipment, contact the ARO at 348-3387/348-2621 for instructions. The ARO will provide regulatory paperwork and oversight. The following protocols must be adhered to:

- An EA-101 Form (Appendix A) must be filled out and submitted to ARO prior to transferring the agent. No select agent can be shipped unless the EA-101 form is complete to be in compliance with Federal regulations.
- Recipient and shipper must have a registration number
- Shipper must receive confirmation in writing that shipment has been received. A copy of receipt will be sent to the ARO.
- The ARO of the recipient provides a completed paper copy or fax of the EA-101 to the sender and to Health and Human Services (HHS) within 2 business days of receipt of the select agent/toxin.
- The recipient immediately reports to HHS if the select agent/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 or was otherwise damaged.
- All shipments of select agents/toxins will meet the packaging requirements defined by IATA "Shipping Infectious and Biological Substances."

### **PACKAGE INSPECTIONS**

The University is only required to inspect suspicious packages. FIU is responsible for specifying who should conduct these inspections. Some of the typical characteristics which should trigger suspicion of letters or parcels are:

- Having any powdery substance on the outside.
- Unexpected or from someone unfamiliar to you.
- Having excessive postage, handwritten or poorly typed address, incorrect titles or titles with no name, or misspellings of common words.
- Addressed to someone no longer with your organization or are otherwise outdated.
- Having no return address, or have one that cannot be verified as legitimate.
- Of unusual weight, given their size, or are lopsided or oddly shaped.
- Having an unusual amount of tape.
- Are marked with restrictive endorsements, such as "Personal" or "Confidential."

- Having strange odors or stains.

Please refer to the FIU Public Safety Department's "Protocol for Identifying and Handling a Suspicious Package" for more information.

### **INVENTORY CONTROL**

It is important that the select agent user keep a record of the agent's location, how it is used, inventory, transfers (external/internal), and destruction and access. Copies of logs will be provided to the ARO during inspections. Researcher will keep record of logs indefinitely.

The following logs are required:

- Name, characteristic and source date of agent
- The quantity acquired, the source and date of acquisition
- Quantity held on the date of the first inventory (toxin only)
- Current quantity held (toxin only)
- The quantity used and dates of the use (toxin only)
- The name of each person who has accessed any select agent or toxin
  - The select agent or toxin used
  - Date removed
  - The amount of toxin used
  - The date agent was returned to storage
  - Quantity of toxin returned
- The quantity transferred, transfer date, recipient's name

### **DESTRUCTION AND DISPOSAL**

Destruction and disposal of select agents must be done in accordance with federal procedures. Select Agents may not be destroyed until a **Notification of the Proposed Destruction of Select Agents Form** documenting the method of destruction, has been submitted by the select agent laboratory to EH&S and approved by the RO. The appropriate federal agency must be notified by the RO prior to the destruction of any select agent biological agents or toxins. Instructions for destroying and disposing of various select agents are provided with the notification form. Please contact the ARO with any questions or concerns at 348-3387/2621.

### **Bacteria and viruses**

When destroying *working* cultures of Select Agent *organisms*, it is not necessary to notify EH&S, 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**.

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

1. Complete and sign the **Notification of Proposed Destruction of Select Agents Form** and fax it to the RO at 348-3574.
2. The RO will notify the PI or lab manager when destruction is approved by CDC/APHIS.
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**. (see p. 26-28 in the FIU Biosafety manual)

### **Toxins**

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

#### **A. Chemical destruction of toxins:**

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

Long sleeved protective clothing (lab coat, gown)  
Gloves and eye protection

1. Complete and sign the **Notification of the Proposed Destruction of Select Agents Form** and fax it to the RO, 348-3574
2. The RO will notify the PI or lab manager when destruction is approved.
3. Work in a fume hood or biosafety cabinet with the sash at the lowest reasonable sash height for safe and effective work.
4. Place plastic backed absorbent paper (bench diaper) on the work surface of the fume hood or biosafety cabinet.
5. Put the Select Agent toxin into solution in the primary container. **DO NOT USE A GLASS CONTAINER.**
6. Place the primary container in a secondary container, such as a beaker or rack.

7. Slowly dispense an equal volume of the concentrations of sodium hypochlorite and/or sodium hydroxide designated in **Table I** 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 30 minutes exposure time. (See **Table I** below 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. Contact EH&S for disposal as **hazardous waste**. (see section 9.0 in the FIU Lab Safety manual)

**B. Steam Sterilization (Autoclaving) of Toxins**

Toxins can be destroyed by autoclaving using the procedure outlined below:

1. Complete and sign the **Notification of the Proposed Destruction of Select Agents Form** and fax it to the RO, 348-3574.
2. The RO will notify the PI or lab manager when destruction is approved.
3. In a 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 puncture-proof container.
5. Place the sharps container in an autoclavable pan.
6. Autoclave at 121° C for 1 hour on liquid cycle (slow exhaust).
7. Document the destruction of Select Agent toxin the laboratory Select Agent inventory logbook.
8. After autoclaving, allow time for materials to cool before handling.
9. Discard the contents and its container as **infectious waste**.

**DO NOT use steam sterilization for destruction of any of the low molecular weight toxins (i.e. mycotoxins, marine and reptile venoms).**

All waste from toxins that are not disposed as infectious waste must be collected by EH&S for disposal as hazardous waste.

**Table 1. Inactivation Procedures for Select Agent Toxins**

At least 30-minutes of chemical contact time should be allowed for complete inactivation of toxin. Any procedure labeled "yes" is an approved procedure for inactivation of the toxin specified.

Select Agent Toxin	Autoclave (1 hour @ 121° C, liquid exhaust)	2.5% Sodium Hypochlorite + 0.25 N NaOH	0.1% Sodium Hypochlorite	1.0% Sodium Hypochlorite	2.5% Sodium Hypochlorite
Abrin <sup>(1)(8)</sup>	Yes	N/A	N/A	N/A	N/A
Botulinum Neurotoxin <sup>(1)(7)</sup>	Yes	Yes	Yes	Yes	Yes
<i>Clostridium</i> <i>perfringens</i> epsilon toxin <sup>(2)</sup>	Yes	N/A	N/A	N/A	N/A
Conotoxin <sup>(3)</sup>	Contact EH&S				
Diacetoxyscirpenol <sup>(4)</sup>	No	Yes	No	No	Yes (3-5%)
Ricin <sup>(1)(7)</sup>	Yes	Yes	Yes	Yes	Yes
Saxitoxin <sup>(1)(7)</sup>	No	Yes	Yes	Yes	Yes
Shigatoxin & Shiga- like ribosome inactivating proteins <sup>(5)</sup>	Yes	Yes	Yes	Yes	Yes
Staphylococcal Enterotoxins <sup>(1)(7)</sup>	Yes	Yes	Yes	Yes	Yes
Tetrodotoxin <sup>(1)(7)</sup>	No	Yes	No	Yes	Yes
T-2 Toxin <sup>(1)(6)</sup>	No	Yes	No	No	No

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. Factsheets on Chemical and Biological Warfare, [www.cbwinfo.com/Biological/Toxins/Cper.html](http://www.cbwinfo.com/Biological/Toxins/Cper.html)
3. Factsheets on Chemical and Biological Warfare, [www.cbwinfo.com/Biological/Toxins/Conotox.html](http://www.cbwinfo.com/Biological/Toxins/Conotox.html)

4. Factsheets on Chemical and Biological Warfare, [www.cbwinfo.com/Biological/Toxins/Verotox.html](http://www.cbwinfo.com/Biological/Toxins/Verotox.html)
5. Factsheets on Chemical and Biological Warfare, [www.cbwinfo.com/Biological/Toxins/mycotoxins.html](http://www.cbwinfo.com/Biological/Toxins/mycotoxins.html)
6. 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 hr. Expose cages and bedding from animals exposed to T-2 mycotoxin to 0.25% sodium hypochlorite and 0.025 N sodium hydroxide for 4 hrs.
7. 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.
8. Fact Sheet from IPCS INCHEM: [www.inchem.org/documents/pims/plant/abruspre.htm](http://www.inchem.org/documents/pims/plant/abruspre.htm)

### Prions

Prions are extremely resistant to conventional inactivation procedures including irradiation, boiling, dry heat and chemicals (formalin, betapropiolactone, alcohols). Most procedures reduce infectivity rather than eliminate it. All treated contaminated materials should be discarded through the **infectious waste** stream and incinerated. Use DISPOSABLE plastic labware whenever possible.

1. Complete and sign the **Notification of the Proposed Destruction of Select Agents Form**.
2. EH&S will notify the PI or lab manager by email when destruction is approved.
3. Inactivate prions by one of the following methods:
  - o Autoclave dry waste at 132° C for 4.5 hours.
  - o Treat large volumes of infectious liquid waste containing prions with 1N NaOH (final concentration) followed by autoclaving at 132° C for 4.5 hours.
  - o Treat with phenol (1:1); guanidine hydrochloride or isocyanate (>4 mol/L); 1N NaOH (final concentration); sodium hypochlorite (>2% free chlorine) for 24 hours.
4. Dispose of inactivated prion waste as **infectious waste**.

### INCIDENCE RESPONSE

Authorized users should ensure that, in cooperation with facility safety, security, and public relations officials, policies and procedures are in place for reporting and investigating unintentional injuries, incidents (e.g. missing biological agents or toxins, unauthorized personnel in restricted areas, or usual/threatening phone calls), or breaches in security measures.

If select agents are discovered missing, released outside the laboratory, involved in worker exposures or infections, or misused, the RO, HHS or USDA should be notified immediately. In

addition, all incidents involving select agents should be reported to local and state public health authorities. Any security breach of a select agent use area must be immediately reported to the RO and Public Safety. By State Statute, Public Safety has jurisdiction over campus crimes. Any security breach will be investigated and prosecuted according to State law.

### **EMERGENCY RESPONSE**

Each academic college, department and laboratory where select biological agents and/or their toxins are stored and/or used must have an Emergency Response Plan. These plans must be coordinated with the FIU Emergency Management Plan.

Authorized users bear the responsibility to document the hazards associated with the use of their respective select biological agents and toxins. Each lab where select agents are stored and/or used must develop appropriate personnel roles, lines of authority, and communication that could go into effect during a man made or natural emergency, and this information must be incorporated into initial and ongoing training in the laboratories.

Development of an Emergency Response Plan should include the following:

- collaboration of facility administrators, scientific directors, authorized users, laboratory workers, maintenance and engineering support staff, facility safety officers, and facility security officials.
- provisions for the immediate notification of and response by laboratory and animal directors, laboratory workers, safety office personnel, or other knowledgeable persons when an emergency occurs.
- establishment of advance coordination with local police, fire, and other emergency responders to assist community emergency responders in planning for emergencies in select agent laboratory and animal areas.
- consideration of circumstances that may require emergency relocation of select agents to another secure location.
- reevaluation and training of employees; conducting exercises of the emergency response plan at least annually.

### **CLINICAL AND DIAGNOSTIC LABORATORIES**

Directors of Clinical or Diagnostic Laboratories that identify certain select agents/toxins from diagnostic or verification testing activities are required to contact the RO and CDC and/or APHIS immediately. Directors must contact EH&S for further instructions.