



Select Agents Program

I. Policy

It is the policy of California State University, Fullerton that all laboratories and campus facilities that will use, transfer, possess, or receive select agents must comply with [Possession, Use, and Transfer of Select Agents and Toxins, 42 Code of Federal Regulations Part 73](#).

II. Authority

Centers for Disease Control <http://www.selectagents.gov/>

7 Code of Federal Regulation Part 121/331

<http://www.selectagents.gov/resources/7%20CFR%20331.pdf>

<http://www.selectagents.gov/resources/9%20CFR%20121.pdf>

[42 Code of Federal Regulations Part 73](#)

III. Scope

This policy applies to University faculty and staff, students, and visitors who receive, possess, use, transfer or acquire Select Agent(s) while participating in any university and non-university sponsored activity at all university facilities.

IV. Definitions

Access Only authorized persons are permitted access to Select Agents. Access to a Select Agents can be limited by either secure storage containers or authorized personnel. For non-laboratory functions including routine cleaning, maintenance and repairs, non-approved individuals will be allowed access to areas where Select Agents are accessible only if they are escorted and monitored by authorized personnel.

Authorized person is an individual who has been approved for access to Select Agents through the successful completion of an FBI security risk assessment as described in 42CFR73.8.

Biological agents are microorganisms (including, but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa), 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.

Responsible Official (RO) is 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 campus Environmental Compliance Manager in Environmental Health and Safety.

Restricted Persons are prohibited from having access to Select Agents. A restricted person is any individual who:

- A. Has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year;
- B. Is under indictment for a crime punishable by imprisonment for a term exceeding one 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 Cuba, Iran, Iraq, Libya, North Korea, Sudan or Syria, or any other country to which the Secretary of State, pursuant to applicable law, has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or
- H. Has been discharged from the Armed Services of the United States under dishonorable conditions.

Select Agents as defined by the CDC and APHIS, means biological agents or toxins deemed a threat to the public, animal or plant health, or to animal or plant products.

- A. A list of select agents can be found at [Select Agents and Toxins](#).
- B. Materials that do not pose a threat to public health can be found at [Select Agent Exclusions](#).
- C. Permissible amounts of select agents can be found at [Permissible Toxic Amounts](#).

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

V. Accountability

- A. **Responsible Official (RO)**
The RO provides the oversight for the University's Select Agents Program. The RO ensures that the university is compliant with all federal laws and regulations that govern the possession, use, and transfer of select agents and

toxins that have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products.

1. Coordinates with CDC regarding the Select Agent Registration process.
2. Maintains an inventory of the principal investigators that are using Select Agents.
3. Notifies the CDC if a Select Agent is depleted or destroyed.
4. Verifying that the requestor is an employee has a current registration, and has an appropriate laboratory or campus facility for the research proposed.

B. Alternate Responsible Official

The Alternate Responsible Official (ARO) is the Biosafety Officer in the Environmental Health and Safety office. The ARO's duties include, but are not limited to:

1. Maintains an inventory of select agents. Review and update annually.
2. Works with the Institutional Biosafety Committee in reviewing research proposals and laboratory protocols involving the possession and use of select agents.
3. Provides select agent specific training to procurement officials and principal investigators, as necessary.
4. Verifies that a select agent has been depleted or destroyed.
5. Documents all select agent activity including inventory, purchases, exchanges, use, and disposal. Maintain records in a secure location.

C. Institutional Biosafety Committee (IBC)

The IBC is the principal advisory group to oversee and review the use of potentially hazardous biological materials brought to the attention of the committee.

D. Principal Investigator

The Principal Investigator is responsible for full compliance with the policies, practices and procedures set forth under federal guidelines and by the University. This responsibility extends to all aspects of biological safety involving the environment and all individuals who enter or work in the Principal Investigator's laboratory or collaborate in carrying out the research. Although the Principal Investigator may choose to delegate aspects of the biological safety program to other laboratory personnel or faculty in his/her laboratory, the Principal Investigator retains ultimate responsibility and is accountable for all activities occurring in his/her laboratory. The PI must be an "Authorized Person." The PI's responsibilities include:

1. Authorization of laboratory personnel, proposing safety practices and equipment, controlling access, security, and transferring or receiving select agents.
2. The PI may not receive agents until they are registered with this program and have received approval from the RO, IBC, and the Federal Health and Human Services Secretary.
3. The PI requesting the use of Select Agents must notify the RO *prior* to the start of any research or classroom activity involving select agents.

VI. Program

A. Registration

All principal investigators must register with the Centers for Disease Control prior to the receipt, use, or transfer of select agents that are on the list in the attached Appendix. PI's must comply with all of the requirements established by the Centers for Disease Control as outlined in 42 CFR 73. Contact the RO, ARO, or EHS (657-278-7233) *prior* to planning any work with select agents.

B. Authorization/Approval

Principal Investigators (PI) interested in working with select agents or toxins must contact the RO in Environmental Health and Safety. 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.

C. Practices and Procedures

Practices and procedures for safe use of select agents will be based upon the conditions set forth in Reference A, CDC-NIH "Biosafety in Microbiological and Biomedical Laboratories" (Sections III through VII and Appendix I) but may be modified by RO and ARO.

D. Training

All personnel that purchase or approve the purchase of select agents must have training on the procedures necessary for the purchase of select agents. Principal investigators that possess, use, transfer, or receive select agents must have training regarding (1) the symptoms of exposure, (2) a post-exposure management protocol, (3) spill cleanup and decontamination, (4) proper use of engineering, administrative and work practice controls, and (5) personal protective equipment, and security requirements for select agent possession and use, (6) purchasing, transfer, shipping, and receiving protocols.

E. Security

All laboratories and campus facilities that purchase, possess, use, transfer, or receive select agents must comply with all of the security requirements established by the Centers for Disease Control and Prevention for the inventory and containment of select agents. CDC minimum recommendations are listed in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) Appendix F.

<http://www.cdc.gov/od/ohs/biosfty/bmb14/b4af.htm>

F. Laboratory Inspections

Laboratories and campus facilities that purchase, possess, use, transfer, or receive select agents must be inspected quarterly by the ARO to ensure that all requirements are being met. If a facility is found to be in non-compliance, the CDC Select Agent Certificate of Registration may be revoked.

G. Engineering Controls

Engineering controls, such as fume hoods and biological safety cabinets, must be used as the primary containment method to limit personnel exposure to select agents. Engineering controls must be: (1) inspected in order to ensure efficient removal of hazards and (2) must have a visual indication of airflow to ensure airflow has fallen below acceptable standards. Notification of laboratory personnel must be made prior to any maintenance that will impact the capture velocity of ventilation systems. Local exhaust ventilation systems including laboratory-type chemical fume hoods and biosafety cabinets must be certified upon installation, after maintenance and annually thereafter. Hood inspection is performed by EHS and/or ARO.

H. Administrative Controls

All principal investigators that purchase possess, use, transfer, or receive select agents must develop operating procedures to ensure safe work practices are being consistently used. EHS and/or ARO will assist PI's in the development of these procedures. PI's must review the procedures annually, or as necessary, to reflect changes. Standard Laboratory Practices for Guidelines for Work with Toxins of Biological Origin are addressed in the BMBL Appendix I.

I. Personal protective equipment

Personal protective equipment appropriate to the select agent or biological toxin must be used to protect personnel from exposure. Personal protective equipment must be approved by EHS and appropriate protection for the select agent used.

J. Depleted or Destroyed Select Agents

The RO or ARO must verify the depletion or destruction of the select agent. It is good practice to have at least 2 people witness and document the destruction of the select agent. The RO must maintain the records of destruction for a minimum of 5 years following the depletion or the destruction of the select agent. If the PI no longer has select agents, the CDC must be notified in writing by the RO to have the PI removed from the registration. The CDC will send a letter to confirm the change.

K. Shipping of Select Agents or Biological Toxins

All select agents and biological toxins must be shipped in accordance with the International Air Transport Association (IATA) requirements as an "Etiologic

Agent with a Dangerous Goods Manifest" and must meet other applicable regulatory requirements and Select Agent specific hazard information. The PI requiring shipment or receipt of Select Agents must notify the RO/ARO prior to shipment of Select Agents. Shipper responsibilities include:

1. Shipper is required to notify CDC of any transportation incident involving a select agent at the CDC Emergency Phone Number (1-800-232-4636), 24 hours a day, 7 days a week.
2. Packages containing select agents are required to be packaged as "Infectious Substances," and labeled with "Infectious Substance and Etiologic Agent" Label.
3. Packaging requirements for select agents require that the shipper's name and phone number appear on the outer package, in order to be used in emergencies.
4. The phone number must be answered 24 hours a day by the shipper in case of emergency.
5. Importers of select agents are also subject to CDC's regulation 42 CFR Part 71.54, ("Importation of Etiologic Agents and Vectors"), and are responsible for obtaining an import permit from the CDC prior to importing Select Agents.
6. For questions regarding shipping or permitting issues please contact the RO or ARO at EHS - (657) 278-7233.

L. Receipt of Select Agents or Biological Toxins

All select agents and biological toxins must be addressed to and received by the Environmental Health and Safety Office prior to delivery to the laboratories. Packages will be picked up by EHS personnel and processed in an appropriate facility on campus. This is to ensure proper shipment, notification, and tracking of select agents. The PI receiving select agents must notify the RO/ARO/EHS prior to the shipment of select agents.

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