



ENVIRONMENTAL HEALTH AND SAFETY

Administrative Policy

Select Agents and Toxins Registration and Use

Source: Environmental Health and Safety

Prepared by: _____
Biological Safety Officer, Environmental Health and Safety

Reviewed by: _____
Director, Environmental Health and Safety

Approved by: _____
Vice Chancellor for Research

Effective Date: June 2018

Applies: Denver Campus and Anschutz Medical Campus

I. Purpose, References, Authority and Responsibility

A. Purpose

1. The purpose of this policy is to ensure the possession, use and transfer of select agents and toxins (SAT) at the University of Colorado Denver | Anschutz Medical Campus is in accordance with federal law and regulations as required by the U.S. Department of Health and Human Services, the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture, Animal and Plant Health Inspection Service.

B. Scope and Applicability

1. This policy applies to all possession, storage, use, transfer and disposal of SAT administered by, conducted by, or under the direction of any employee or agent of CU Denver | Anschutz in connection with his or her responsibilities there.

C. References

1. Code of Federal Regulations, Title 42 CFR Part 73; Possession, Use and Transfer of Select Agents.

I. Purpose, References, Authority and Responsibility (continued)

C. References (continued)

2. Code of Federal Regulations, Title 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins
3. Code of Federal Regulations, Title 7 CFR Part 331, Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Biological Agents and Toxins
4. NIH Grants Policy Statement
5. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
6. CDC/NIH, Biosafety in Microbiological and Biomedical Laboratories 5th Edition
7. OSHA, 29 CFR 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories

D. Related Policies

1. CU Denver | Anschutz Institutional Biosafety Committee Policy and Procedures
2. CU Denver | Anschutz Fiscal Policy, Chapter 4
3. CU Denver | Anschutz Access Control and Physical Security Policy

E. Roles and Responsibilities

1. Office of the Chancellor and Office of the Vice Chancellor for Research (OVCR)
 - a. The Office of the Chancellor has primary responsibility for regulatory compliance and policies for the Denver and Anschutz campuses.
 - b. The Chancellor has delegated this responsibility to the OVCR.
 - c. The OVCR, in keeping with federal regulation, will appoint a Responsible Official (RO) and, as needed, any Alternate Responsible Official (ARO).
2. Responsible Official
 - a. The RO will exercise management oversight of and compliance with the federal Select Agents Regulations on the Denver and Anschutz campuses.
 - b. The RO will retain the authority and responsibility to immediately bring to the attention of the OVCR any errors, omissions or discrepancies in the application of these policies, or in compliance with the Select Agents Regulations.
 - c. The RO has the authority to revoke an individual's access to SAT if it is deemed necessary for the safety of the individual or others.
 - d. The RO will report any incidents, exposures or deficiencies to the CDC and/or APHIS

I. Purpose, References, Authority and Responsibility (continued)

3. The Institutional Biosafety Committee (IBC)
 - a. The IBC has the responsibility to review and approve work with SAT on the Denver and Anschutz campuses. It is the responsibility of the IBC to review such projects for physical containment of materials, and protection of the public and environment from exposures.
4. The Principal Investigator (PI)
 - a. It is the responsibility of all PIs throughout CU Denver | Anschutz to comply with this policy.
 - b. The PI must report all incidents, exposures or discrepancies immediately to the RO.
5. Authorized Persons with Access to SAT
 - a. Authorized persons are required to attend special training as prescribed by the RO. Authorized persons must handle SAT safely, secure it properly, update inventories regularly, dispose of materials appropriately, and report any deficiencies to the PI and RO.
6. Department of Environmental Health and Safety (EHS)
 - a. EHS will manage the day-to-day operations and compliance with the Select Agents Regulations.

F. Appendices

1. Appendix A: Definitions
2. Appendix B: Requirements for Possession of Select Agents and Regulated Amounts of Select Toxins
3. Appendix C: Requirements for Possession of Permissible Amounts of Select Toxins

Appendix A

Definitions

I. 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 infection, disease, death or other biological malfunction in a human, animal, plant, or other living organism, or the deterioration of food, water, equipment, supplies, or materials of any kind, or deleterious alteration of the environment.

II. Entity

Any federal, state, or local government agency, or academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

III. Principal Investigator

The one individual designated by an entity to direct a project or program, and who is responsible to the entity for the scientific and technical direction of that program or project.

IV. Select Agent

All those select agents, toxins and genetic elements included in the Select Agents Regulations: 42 CFR Part 73, 9 CFR part 121, and 7 CFR Part 331.

V. Toxin

The toxic material or product of plants, animals, microorganisms (including, but not limited to bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or a recombinant or synthesized molecule whatever its origin or method of production, and which 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, homology or derivative of such a substance.

VI. Authorized Person

An individual who has been approved by the RO for access to select agents through the successful completion of a security risk assessment conducted by the Federal Bureau of Investigation.

Appendix A (continued)

Definitions

VII. Access

Means an individual has possession of an SAT (i.e., ability to carry, use, or manipulate), or the ability to gain possession of an SAT. Only authorized persons are permitted access to select agents. Access to SAT can be limited by either security containers, or by escorts. For non-laboratory functions, including routine cleaning, maintenance or repairs, non-approved individuals will be allowed access to areas where SAT is accessible only if they are escorted and monitored by an authorized individual.

Appendix B

Requirements for Possession of Select Agents and Regulated Amounts of Select Toxins

I. Select Agent Registration

- A. PIs considering the use of SAT in their research must register their intent with their department chair, the IBC, and the RO. This applies to the use of excluded select agents and non-regulated amounts of select toxins, as well.
- B. The IBC will review and approve research proposals. PIs who fall under the regulations will register with the CDC and/or APHIS, in collaboration with the RO.

II. Personnel Reliability

- A. Prior to gaining access to SAT, individuals will undergo a security risk assessment and be reviewed through the university's Personnel Reliability Program (PRP), coordinated by the RO. The PRP is not applicable to individuals using select toxins below the permissible quantity limits.

III. Training

- A. Select agents training and practical drills/exercises, coordinated by the RO, will be required annually for all individuals with access to SAT.
- B. Visitors to registered spaces must be trained in the risks and regulations associated with the spaces.
- C. EHS will provide general training in CU Denver | Anschutz policies and procedures required for any individual working with infectious agents, recombinant nucleic acids, hazardous chemicals or radioactive materials.
- D. The PI must demonstrate to the satisfaction of the IBC (generally by CV, bio-sketch, or on-the-job training records) that they and their staff are adequately trained to work safely with SAT.

IV. Facilities and Security

- A. Inspection and approval of the applicant's laboratory will be made at the discretion of the IBC and/or the RO, in accordance with federal requirements.
- B. Facilities are subject to inspection by federal agencies (CDC, USDA, etc.), as well as internal inspection by the RO.
- C. Stored SAT must be secured in a locked container, which must remain locked at all times. If a lock box is used, it must be affixed to a refrigerator/freezer/cabinet. SAT not in storage must be controlled and maintained under constant surveillance by an authorized person.

Appendix B (continued)

Requirements for Possession of Select Agents and Regulated Amounts of Select Toxins

V. Records

- A. The RO must keep an up-to-date, accurate list of all individuals approved for SAT access.
- B. The RO must maintain records pertaining to:
 - 1. Inspections
 - 2. Safety, security and emergency response plans
 - 3. Training
 - 4. SAT transfer documents
 - 5. Incident reports
 - 6. Access logs
 - 7. SAT destruction records
- C. The PI must maintain a current and accurate SAT inventory.
- D. All records must be maintained for a minimum of three years.

VI. Transfers

- A. Extramural transfers of select agents may not occur without prior authorization by the CDC and/or APHIS, and the ROs at the facilities of the transferor and recipient.
- B. Extramural transfers of commercially available select toxins is prohibited
- C. Intramural transfer of SAT must be approved by the RO before the transfer occurs.

VII. Destruction and Disposal

- A. Destruction of SAT must be done in accordance with documented methods approved by the RO and IBC.

Appendix C

Requirements for Possession of Permissible Amounts of Select Toxins

I. Registration for Possession and Use of Select Toxins

- A. Select toxins are not regulated by the federal government if the amount under the control of a PI does not exceed, at any time, the published permissible amount established in the Select Agent Regulations.
- B. Any PI who will need to obtain, possess, and/or use select toxins in quantities that do not exceed the permissible amount is required to register with the IBC and complete all appropriate application forms.
 - 1. A letter of approval from the PI's department chair or division head shall accompany the submitted forms.

II. Roles and Responsibilities

- A. IBC
 - 1. Review and approve applications from PIs requesting possession and use of permissible amounts of select toxins.
 - 2. Report PIs with new approval for use of select toxins to the RO and EHS.
- B. RO and EHS
 - 1. Maintain a list of PIs authorized to use select toxins at permissible amounts.
 - 2. Assist PIs in developing standard operating procedures (SOPs) for the safe use, storage and destruction of select toxins.
 - 3. Perform annual audits of PIs' laboratories to review compliance with this policy, and to confirm select toxins on site are within permissible amounts.
 - 4. Report to the CDC and/or APHIS incidents of unauthorized PIs in possession of regulated amounts of select toxins.
- C. PI
 - 1. Prepare appropriate written SOPs for research processes involving select toxins, to address inventory, containment, personal protective equipment (PPE), disposal, spills, exposures and incident reporting.
 - 2. Ensure staff have been appropriately trained prior to accessing select toxins.
 - a) Documented on-the-job training must include review of SOPs, hazards and symptoms of exposure (safety data sheets), and the proper use of containment equipment and PPE.

Appendix C (continued)

Requirements for Possession of Permissible Amounts of Select Toxins

III. Requirements and Procedures

A. Purchasing Select Toxins

1. Select toxins will not be purchased until approval is granted by the IBC.
2. To ensure amounts on hand are within permissible limits, amounts purchased must be no more than the minimum required for research.
3. Only one designated lab member may be allowed to purchase select toxins, to prevent making duplicate purchases and exceeding permissible amounts.

B. Inventory, Storage and Security

1. A select toxin inventory log will be maintained by the PI and updated when the toxin is:
 - a) Acquired by purchase or transfer
 - b) Removed from use
 - c) Depleted by use or destruction
2. The select toxin inventory log will record:
 - a) Type of toxin
 - b) Date and time of event
 - c) Name of individual performing event
 - d) Type of event (e.g., purchase, removal for use, destruction)
 - e) Amount of toxin remaining following event
3. Toxins shall be stored with compatible materials, within secondary containers.
4. Stored select toxins must be secured in a locked container, which must remain locked at all times. If a lock box is used, it must be affixed to a refrigerator/freezer/cabinet. Select toxins not in storage must be controlled and maintained under constant surveillance by an authorized person.

C. Destruction and Waste Management

1. An SOP must describe the accepted waste management procedure for the specific toxin.
2. Empty vials containing trace amounts of unused toxin must be disposed of as chemical waste through EHS Hazardous Materials Division.

Appendix C (continued)

Requirements for Possession of Permissible Amounts of Select Toxins

3. Leftover undiluted toxin or stock solutions of toxin must be disposed of as chemical waste through EHS Hazardous Materials Division.
4. Liquid waste, such as cell culture media, containing toxin must first be treated to inactivate any biological hazards. Following inactivation the liquid waste must be disposed of as chemical waste through EHS Hazardous Materials Division.
5. Solid waste, such as tissue culture flasks, containing trace amounts of toxin must be disposed of in the yellow Regulated Medical Waste tubs.
6. Animals treated with toxin must have an appropriate Vivarium SOP posted indicating proper disposal of carcasses.

D. Transfers

1. Extramural transfers of commercially available select toxins is prohibited
2. Intramural transfer of permissible quantities of select toxins must be approved by the RO prior to transfer.
3. The transferring PI must use due diligence to:
 - a) Ensure the recipient has a legitimate need to handle or use such toxins
 - b) Report to the Federal Select Agent Program if a known or suspected violation of federal law, or suspicious activity related to the toxin is detected

E. Incident Responses to Accidental Release or Personal Exposure

1. An SOP must describe procedures for response to accidental release of or personal exposure to select toxins.
2. In the event of an accidental release or personal exposure to select toxins, the RO must be immediately notified of the incident.
3. Persons experiencing exposure (e.g., skin or mucous membrane contact, ingestion, needle stick) to select toxins will immediately seek medical care.