

VIRGINIA COMMONWEALTH UNIVERSITY

SELECT AGENTS INFORMATION PAGE

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I. DEFINITION: “Select Agents” are defined by the [Centers for Disease Control](#) (CDC) as: “specific agents which are considered capable of rendering substantial harm to humans”.

II. REGULATIONS:

A. Environmental Protection Agency: [Antiterrorism and Effective Death Penalty Act of 1996](#) : Enacted with intent of acting as a deterrent to biological terrorism through controlling access to acutely toxic and infectious agents.

B. National Institutes of Health/Centers for Disease Control: ["Additional Requirements for the Transfer or Receiving of Select Agents"](#) (42 CFR Part 72)”: Identifies biological agents and toxins which are subject to select agents restrictions, imposes strict institutional requirements on the transfer, receipt, use, and destruction of select agents, and requires designation of “Responsible Facility Official (RO),” whose duties include managerial oversight of the transfer process.

C. Department of Health & Human Services/Department of Agriculture: [“Public Health Security and Bioterrorism Preparedness Act of 2002”](#)”: retains the requirements of 72 CFR 42 but adds stipulations for security clearance of personnel with access to select agent and enhanced measures for securing select agents.

D. Centers for Disease Control: [Final Rule of 42 CFR Part 73, Possession, Use, and Transfer of Select Agents and Toxins](#): The Final Rule governs the possession, use and transfer of select biological agents and toxins ("select agents") that pose a potential threat to public health and safety.

III. SELECT AGENTS LIST:

A. Select Agents and Biological Toxins: The most current listing of substances classified as select agents can be viewed at the [CDC National Select Agent Registry](#) .

B. Excluded Attenuated Strains. All facilities using, possessing, or transferring live select agents listed in Appendix A of 42 CFR 72 are required to register with HHS immediately, unless the agent is an attenuated strain which is identified on the [Exclusion List](#).

IV. EXEMPTIONS:

A. Biomedical Research Exemption:

1. According to 42 CFR Part 72: “Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD₅₀ for vertebrates of more than 100 nanograms per kilogram body weight,” and “national standard toxins required for biologic potency testing as described in 9 CFR Part II 3” are exempt from registration requirement. Researchers must be aware, however; that HHS has set [strict quantity limits](#) for all affected toxins: if quantity limits are exceeded, the biomedical exemption is nullified and select agent registration with HHS is mandatory.

2. The NIH advises that the [Registry of Toxic Effects of Chemical Substances](#) database, maintained by the National Institute for Occupational Safety & Health, be used as a guide when determining the LD₅₀ of a select agent.

B. Possession prior to 42 CFR 72: The current HHS regulations include use, *possession* and transfer of select agents: claims of exemption due to possession prior to 42 CFR 72 are not valid.

V. SELECT AGENTS: UNIVERSITY POLICIES

A. Chain of Custody: Unless covered under the biomedical exemption of included on the exclusion list of attenuated strains, all receipt/shipment of select agents must be preapproved by the Responsible Facility Official (RO). Principle investigators may not take custody of any select agent until full compliance with regulatory requirements and university policies has been demonstrated. Please contact the [Biosafety Office](#) for arrange a meeting with the university's acting RO.

B. Identification/Tracking: The university utilizes several methods for identifying/tracking select agents:

1. Select Agent Registration: The IBC conducts an annual program which registers types, locations, and quantities of all select agents; including those covered under the biomedical exemption. This effort is intended to ensure that researchers do not exceed allowable quantities under the biomedical exemption and to identify possible unreported use of materials not included under exemption/exclusions

2. Protocol Review: Select agents use is further tracked through IBC review and overview of research protocols including:

a. Memorandum of Understanding and Agreement (MUA) required for registering *in vitro* research involving rDNA/biological hazards.

b. IACUC Protocol Appendix C required for registering *in vivo* research involving chemical/biological/rDNA hazards.

3. Laboratory Inspections: The Office of Environmental Health & Safety - [Chemical/Biological Safety Section](#) (CBSS) conducts annual safety inspections within all university laboratories under the auspices of the IBC. The inspections involve review of active IBC protocols and the laboratory [Chemical Hygiene Plan](#) , in conjunction with a full inspection of conditions within the laboratory.

4. Chemical Waste Disposal Pick-Ups/Laboratory Clean-Outs: CBSS chemical waste technicians are sufficiently trained to allow identification and proper securing of any select agents encountered during routine chemical waste management operations. If select agents (in nonexempt or exempt from) are encountered the RO is notified immediately.

B. Special Handling Considerations:

1. Research involving select agents is restricted to fully trained staff with access to adequate work facilities and personal protective equipment (PPE). Standard Operating Procedures which detail proper work methods, engineering controls, PPE, and emergency response procedures must be specified in the applicable research protocol (MUA/IACUC Appendix C) and the laboratory [Chemical Hygiene Plan](#).

2. When doubts exist regarding the integrity of vessels holding suspected select agents, all university staff are advised *not* to disturb such containers – contact CBSS immediately at 828-1392 for assistance.

3. Never handle any vessel suspected of containing select agents without proper PPE. At a minimum PPE should include:

a. Two layers of examination gloves.

b. Laboratory coat/proper laboratory attire.

c. Safety goggles and or face shield.

d. If potential for aerosolization exists, use of an N-95 or other respirator type will also be necessary. Respirators may not be used without prior participation in the [University Respiratory Protection Program](#).

4. Following handling of select agents, researchers should carefully remove examination gloves and wash hands thoroughly with soap and warm water.

5. In the case of a spill involving a select agent, leave the area immediately and contact CBSS at 828-1392.

6. Report any suspected exposure to select agents to [Employee Health Services](#) immediately.

C. Disposal: The National Institutes of Health/Centers for Disease Control instruct facilities to deplete or destroy all select agents (to include exempt and nonexempt materials) on site prior to disposal.

1. Depletion: Refers to total usage of the select agent during research procedures. It strongly advised that CBSS be provided with “empty” containers to ensure proper destruction/disposal of any residue.

2. Destruction: Involves the use of a strong oxidizing agent followed by steam sterilization. Following destruction the waste products must be disposed of as regulated medical waste. On-site destruction of concentrated select agents should only be conducted by CBSS. Laboratories wishing to treat wastewater contaminated with trace amounts of select toxins should contact the [Biosafety Office](#) prior to proceeding with destruction event.

3. Recycling: Provided that containers are unopened and expiration dates have not been exceeded, surplus toxins in quantities not exceeding the biomedical exemption may be transferred between university researchers. In order to qualify for toxin transfer the PI must first register with the university select agent registration program, verify that the agent has been addressed on the laboratory [Chemical Hygiene Plan](#)/applicable IBC protocol review form, and demonstrate that work/storage facilities, security, and staff training are adequate.

For additional information regarding select agents or other biohazard concerns, contact [Mike Elliott](#) at 400-4984.