

5.5 Restricted Research Activities

5.5.1 Select Agents

At UAB possession, receipt, use, storage, transfer, and disposal of select agents is authorized by permit only and coordinated through the University's Responsible Official (RO).

In response to the mandates of "The Antiterrorism and Effective Death Penalty Act of 1996", additional shipping and handling requirements were placed on facilities that transferred or received a list of agents deemed agents of mass destruction. As of April 15, 1997, commercial suppliers of "Select agents" as well as government agencies, universities, research institutions, individuals and private companies seeking to transfer or obtain regulated "select agents" are required to register with the *Centers for Disease Control and Prevention* (CDC) as a registered facility.

On December 13, 2002 the Department of Health and Human Services and the Department of Agriculture published interim rules governing the way select agents and toxins are to be managed within the United States. The final rule published March 1, 2005 implements provisions of the Public Health and Security and Bioterrorism Preparedness and Response Act of 2002 and was designed to protect public health and safety, animal and plant health, and animal and plant products. [Click here](#) to access the most recent select agent rules and regulations.

The list of HHS and USDA [select agents](#) and related FAQs are available on the respective website as well as the [UAB OH&S](#) website.

UAB Occupational Health & Safety serves as the facilitator and provides University oversight (Responsible Official) required by the regulation. The Responsible Official (RO) is a presidential appointment currently held by the Assistant Vice President for Occupational Health and Safety. An Alternate RO (ARO) has been also appointed to act on the ROs behalf when needed. All possession, use, transfer, and disposal of select agents **must** be coordinated through the Responsible Official or the Alternate Responsible Official.

Research involving select agents must be reviewed by the Institutional Biosafety and/or Chemical Safety Committee before initiation to provide time for amending the UAB facility (entity) registration with the appropriate federal groups.

5.5.1.1 Principal investigators who use, transfer, store, or dispose of select agents must register the project (Appendix G and/or H) and obtain a permit for use from UAB Occupational Health & Safety **before** material may be received, used, transferred or disposed.

5.5.1.2 Complete UAB Form ASA to apply for permit. Allow three to four weeks for application processing, information gathering, and review by UAB Safety Committee(s) and federal regulatory agencies (HHS or USDA). During this time the applicant may be invited to meet with the appropriate UAB Safety Committee representatives to discuss details of the permit and vice versa. Upon review and approval by the appropriate Safety Committee(s), a permit of use and permit system procedures will be issued to the principal investigator (permit holder).

5.5.1.3 PIs, employees, and labs must conform to all requirements of 42 CFR 73, 7 CFR 121, and/or 9 CFR 331, USA PATRIOT Act of 2001, and any other applicable rules and regulations before permits will be issued.

5.5.1.4 "Restricted persons" as defined by 18 U.S.C. 175(b) may not possess, ship, transport or receive select agents. Specific, limited access approval may be requested by the RO from HHS/USDA on a case-by-case basis.

5.5.1.5 Training sessions are conducted by UAB Occupational Health & Safety for all active select agent program participants at permit time with updates at least annually.

5.5.2 Attenuated strains of material on the select agents list

Certain strains of biological agents exempt from federal regulations qualify for additional security due to the high profile of the agent or implications of use that may be associated with them. Therefore, at UAB, facilities receiving, storing, using, or have in their possession attenuated strains of select agents approved for human or animal vaccination purposes by FDA or other recognized national or international organization and used for research purposes or administered in a manner other than as originally intended by the manufacturer and not already regulated by the select agent regulations, must follow the additional practices and procedures as described below:

5.5.2.1 Notify UAB Biosafety and the Institutional Biosafety Committee of intent to obtain and use the agent by completing a Request for Exemption (SA Ex-B) and a Project Registration form (Appendix G and/or H). Material may not be obtained or used until written IBC approval is granted.

5.5.2.2 Control access to areas where agents are stored and used. If the lab is left unattended, lock it.

5.5.2.3 Agents must be stored in a lockable storage box or refrigerator/freezer, when not in use. Access to the agents must be strictly controlled.

5.5.2.4 An up to date inventory must be maintained and available to UAB Biosafety upon request.

5.5.2.5 A list of persons with access to the agent must be maintained and available to UAB Biosafety upon request. Only authorized persons may have access to the agent.

5.5.2.5 Know who is in the laboratory. Only authorized persons should have access to the laboratory. UAB identification badges should be visibly worn.

5.5.2.6 Agents that are resistant to disinfectants or that persist in the environment (i.e. spores) require that strict adherence to cleanliness be followed. Aerosol generating activities must be confined to annually certified biosafety cabinets or other closed systems to reduce agent dispersal. Laboratory waste associated with the agent must be autoclaved on-site and arrangements made through UAB Biosafety and the HMF for final treatment by incineration. Animal carcasses must be double bagged and arrangements made through UAB Biosafety and the HMF for final treatment by incineration.

5.5.3 Non-viable agents on the select agents list

5.5.3.1 Laboratories receiving or in possession of non-viable select agents must maintain documentation confirming the non-viable status of each batch of such agents. Documentation may include statement of non-viability from the source

company, PI or institution, or in-house testing results. Documentation must be available to OH&S during site visits or upon request.

5.5.3.2 Notify UAB Biosafety of intent to obtain and use the non-viable agent by completing a Request for Exemption (SA Ex-B) and a Project Registration form (Appendix G and/or H).

5.5.3.3 Fixed tissues that bear or contain select agents are currently not subject to select agent regulations

5.5.3.4 Non-viable select agents are currently not subject to select agent regulations.

5.5.4 Select agent toxin exclusions

5.5.4.1 Principal Investigators who possess one of the select agent toxins and wish to apply for a toxin exclusion from the select agent regulation must complete the UAB Form SA-ExT and a Project Registration form (Appendix G and/or H).

5.5.4.2 If the total aggregate amount of a select agent toxin (purified form in combination with impure forms) under the control of a principal investigator does not, at any time, exceed the following amounts, that toxin will not be subject to select agent regulations. **Inventory and disposal/destruction record of toxin(s) must be maintained by PI to confirm quantities do not exceed exclusion limits.**

Abrin	≤ 100 mg
Botulinum neurotoxin	≤ 0.5 mg
<i>Clostridium perfringens</i> epsilon toxin	≤ 100 mg
Conotoxins	≤ 100 mg
Diacetoxyscirpenol (DAS)	≤ 1,000 mg
Ricin	≤ 100 mg
Saxitoxin	≤ 100 mg
Shigatoxin	≤ 100 mg
Shiga-like ribosome inactivating proteins	≤ 100 mg
Staphylococcal enterotoxins	≤ 5 mg
Tetrodotoxin	≤ 100 mg
T-2 toxin	≤ 1,000 mg

5.5.4.3 Inventory and waste disposal records must be made available to UAB OH&S upon request.

5.5.5 Select agents in clinical or diagnostic samples

Clinical and diagnostic laboratories are exempt from the select agent regulations **if all of the following apply:**

5.5.5.1 The select agents involved in the laboratory activities are contained in diagnostic specimens or in isolates from specimens presented for diagnosis, verification, or proficiency testing; **and**

5.5.5.2 Upon identification of a select agent as the result of diagnosis or verification, the Laboratory Director/Manager or designee immediately reports to the UAB RO any of the following: HHS SAs Ebola viruses, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito) Variola major (Smallpox virus), Variola minor (Alastrim), *Yersinia pestis*; Overlap agents *Bacillus anthracis*, Botulinum neurotoxins, *Brucella melitensis*, *Francisella tularensis*, Hendra virus, Nipah virus, Rift Valley fever

virus, or Venezuelan equine encephalitis virus and/or any select agent listed on the USDA/APHIS list of animal agents and toxins; **and**

- 5.5.5.3** After the diagnosis, verification, or proficiency testing the lab must have written approval from the UAB RO to either transfer the specimens or isolates containing a select agent to a facility eligible for receiving them under this part, or destroy them on-site by autoclaving, incineration, or by a sterilization or neutralization process sufficient to cause inactivation;
- 5.5.5.4** The lab transfers or destroys those select agents used for diagnosis or testing within seven days after identification, unless directed otherwise by the Federal Bureau of Investigation or other law enforcement entity after the UAB RO has consulted with the HHS Secretary; **and**
- 5.5.5.5** The lab transfers or destroys those select agents used for proficiency testing within 90 days after receipt; **and**
- 5.5.5.6** The lab submits to the UAB RO a record of the identification and transfer or destruction on the APHIS/CDC Form 4 – Report of the Identification of a Select Biological Agent or Toxin in a Clinical or Diagnostic Laboratory which will be submitted to APHIS/CDC within seven calendar days after identification.
- 5.5.5.7** The UAB RO/ARO will file reports with CDC/HHS and/or APHIS/USDA as appropriate upon notification from said laboratory. **Lab staff and PIs do not file directly with APHIS/CDC.**

5.5.6 Requesting Exemptions from the Select Agent Regulation

The HHS Secretary or the USDA Administrator may grant case-by-case exemptions to individuals or entities upon showing of good cause that the exemption is consistent with protecting animal or plant health, animal or plant products, or regulation of the type and/or form of the agent is not necessary to protect public health and safety.

To apply for an exemption not covered under the toxin exclusion:

- 5.5.6.1** Submit to the UAB RO a completed APHIS/CDC Form 5 - Request for Exemption of Select Biological Agents and Toxins for Public Health or Agricultural Emergency or Investigational/Experimental Product.
- 5.5.6.2** Until such time as the RO receives notification or denial of exemption from APHIS/CDC, the agent must be considered regulated and handled as such.

5.5.7 Denial, Revocation, or Suspension of Registration

CDC and APHIS may deny, revoke, or suspend any or all activities of an individual PI and/or the entire institution if they identify issues of failure to comply with the select agent regulations. The causes for this type of action may include, but are not limited to:

- 5.5.7.1** There are repeated violations of the containment or security requirements
- 5.5.7.2** Possession, receipt, use, or transfer of a select agent by a “restricted person” has not been disclosed

5.5.7.3 An authorized user has undisclosed involvement with an organization that engages in domestic or international terrorism or intentional crimes of violence

5.5.7.4 The HHS Secretary or USDA Administrator determines that such action is necessary to protect human health and public security, animal or plant health, or animal or plant products.