

Select Agent Program

The Office of Environmental Health and Safety via its Chemical / Biological Safety Section (CBSS) provides oversight and administration of the VCU Select Agent Program. The VCU Biosafety Officer is the University's designated Responsible Official (RO) for the Select Agent Program.

The list of agents and toxins classified by the Federal government (USDA and CDC/HHS) as Select Agents are those agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products. Any possession, use, transfer or shipment of these materials is strictly controlled by regulation. For the most up to date listing, please check the <u>Select Agents</u> and <u>Toxins List</u>.

Principal Investigators considering work with any of these materials must first contact the VCU Biosafety Officer to initiate the approval process which consists of security and containment assessments, permits, personnel security clearances and other necessary paperwork. All registration activities for these agents must be coordinated through the Biosafety Office; researchers cannot register directly with the USDA or CDC. Be aware that VCU/Federal approval can take 6 months or more to complete in advance of any project. A detailed listing of steps to complete registration is available from the VCU Biosafety Office. General information on select agents and toxins can be found on the Federal Select Agent Program website.

Note that the following are also considered select agents and require full registration:

- 1. Nucleic acids that can produce infectious forms of any of the select agent viruses listed (e.g. nucleic acids from positive strand RNA viruses: Tick-borne encephalitis complex (flavi) viruses, and the togaviruses (Venezuelan Equine Encephalitis virus and Eastern Equine Encephalitis virus).
- 2. Recombinant nucleic acids that encode for the functional forms of any toxin listed if the nucleic acids
 - can be expressed in vivo or in vitro OR
 - are in a vector or recombinant host genome and can be expressed in vivo or in vitro
- 3. Select agents and toxins listed that have been genetically modified.

Certain attenuated strains are excluded from the select agent regulations provided there is no reintroduction of factor(s) associated with virulence or other manipulations that modify the attenuation to restore or enhance virulence. A current list of excluded strains can be found via the <u>Select Agents and Toxins Exclusions</u> website. Note that the use of these strains at VCU still requires university registration for the purposes of monitoring inventories and intra-university transfers.



Some types of diagnostic work with select agents are exempt from full federal registration, but restrictions apply. Please contact the VCU Biosafety Officer to discuss diagnostic work or work with non-confirmed specimens.

Select agent toxins do not require full federal registration if the amount under the control of a principal investigator, veterinarian or treating physician does not exceed, at any time, the amounts listed in the <u>Permissible Toxin Amounts</u> on the Select Agent website. The use of these toxins also requires university registration for the purposes of monitoring inventories and intra-university transfers.

Failure to comply with Select Agents and Toxins federal regulations is punishable by both fines and imprisonment.

If you have questions about select agents and toxins, email the <u>VCU Biosafety Officer</u> or call 804-400-4984.