

Rice University
Select Agents and Toxins
Guidelines and Procedures



Environmental Health and Safety
MS 123
P.O. Box 1892
Houston, TX 77251-1892

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Introduction

Any laboratory interested in research using regulated biological select agents listed in the *Federal Select Agent Program* must contact Rice Environmental Health and Safety prior to work. The purchase, use, storage, and transfer of these materials are highly regulated by the *US Department of Health & Human Services* as a potential public biosafety threat and therefore must have the proper administrative approval before any work commences. Information and lists of select agents and toxins can be found at <http://www.selectagents.gov/>.

Authorization

Prior to conducting research using select agents or toxins the researcher must first obtain an approved registration from *Federal Select Agent Program*.

Once the laboratory has fulfilled all federal requirements and secured a registration, the Principal Investigator (PI) must notify Environmental Health and Safety to assess the biocontainment and security within their facility. Approval for ordering these materials shall be authorized by the Director of Environmental Health and Safety, the Department Chair and/or the Dean/VP of the school or division as outlined in the Rice University Policy No. 313.

If the material is being imported from a foreign supplier or collaborator the following may be needed:

- *CDC Etiologic Agent Import Permit* – <http://www.cdc.gov/od/eaipp/>
- Transfer agreement letter from Rice Office of Technology Transfer - <http://ott.rice.edu>

Training

All researchers must complete the following Rice EHS courses:

- General Laboratory Safety
- Biosafety and Bloodborne Pathogens

The PI must provide specific training on handling, storage, and disposal of the specific biologic agent. All researchers should be aware of the hazards and be provided any available and applicable medical surveillance.

Reporting

The PI must report all suspected theft, loss, release, or occupational exposure of select agent or toxin to the *Federal Select Agent Program* immediately.

Any persons suspected of being occupationally exposed must also contact Rice EHS and Risk Management.

Transfers

The PI must obtain permission from the *Federal Select Agent Program* when transferring materials to another institution. The transfer of any regulated biologics to any private or foreign entity without clearance from the *Federal Select Agent Program* and/or *US Department of Commerce* is strictly prohibited.

Recordkeeping

- A laboratory specific Biosafety Plan must be submitted and approved by Rice EHS
- All communications with federal agency should be copied into the Biosafety Plan
- Training documents for individuals
- Inventory and usage logs should be kept for each agent

Restrictions and Exemptions

The following toxins are not regulated if the amount under the control of the Principal Investigator does not exceed the permissible amount listed below:

HHS Toxins [§73.3(d)(3)]	Amount
Abrin	100 mg
Botulinum neurotoxins	0.5 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol (DAS)	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D, and E)	5 mg
T-2 toxin	1000 mg
Tetrodotoxin	100 mg

The *Federal Select Agent Program* provides guidance updates on restricted experiments that may confer resistance to current medical treatments or increase lethality of the biological agent. These procedures are also covered under the *NIH Dual Use Research of Concern (DURC)* policy.

References

42 CFR Part 73 – provisions set forth under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* for the protection of public and animal health

7 CFR Part 331 - provisions set forth under the *Agricultural Bioterrorism Protection Act of 2002* for the protection of plants

9 CFR Part 121 – provisions set forth under the *Agricultural Bioterrorism Protection Act of 2002* for the protection of animals

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern