

POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

Introduction

Select agents include both microorganisms and toxins that have been specifically identified as potential agents of bioterrorism. In response to terrorism concerns, the Public Health Security and Preparedness and Response Act of 2002 restricts the possession and use of these agents. The Act also requires ASU to collect and maintain information on the location and use on campus of any select agents or toxins. All ASU personnel are responsible for immediately contacting the Biosafety Officer to report current possession of, or plans to acquire, any of the listed agents. Failure to provide notice may result in civil and criminal liability for individuals and ASU. All work with select agents and toxins at ASU must be approved by the Institutional Biosafety Committee (IBC). The entire process of obtaining registration in the Select Agent Program takes approximately six months to one year to complete and includes extensive documentation to comply with requirements.

Applicable ASU Policies

- EHS 112 - Biosafety and the Possession, Use, and Transfer of Select Agents and Toxins
- EHS 405 - Shipping and Receiving Hazardous Materials

Applicable ASU Guidelines

- Biosafety Manual
- Biological Hazardous Waste Management Compliance Guidelines
- Lab-specific standard operating procedures (SOPs) are required; EH&S has a template on the [Biosafety website](#) that can be used to generate SOPs.

Applicable Regulations

- 42 CFR Parts 72 and 73 - Possession, Use, and Transfer of Select Agents and Toxins
- 7 CFR Part 331 and 9 CFR Part 121 - Agricultural Bioterrorism Protection Act of 2002, Possession, Use, and Transfer of Select Agents and Toxins

Summary of Requirements

- IBC registration and approval of all work with select agents and toxins;
- The Principal Investigator completes and submits [EHS form 112C](#) located on the ASU Office for [Research and Sponsored Projects Administration](#) website;
- Either the Centers for Disease Control and Prevention (CDC) or Animal and Plant Health Inspection Service (APHIS) approves participation in the Select Agent and Toxin (SA&T) Program after receipt of the following documentation:
 - Application to the CDC or APHIS to possess, use, or transfer a select agent or toxin (SA&T);
 - Designation of a Responsible Official (RO);
 - Security clearances through the Federal Bureau of Investigation for any employees working with SA&T;
 - Development of a comprehensive safety plan(s) for working with the agent(s) per *Biosafety in Microbiological and Biomedical Laboratories*, National Institutes of Health, and Occupational Safety and Health Administration guidelines;

Development and implementation of an emergency response plan;
Content for required training;
Forms for recordkeeping;
A written policy and plan to conduct an annual inspection of SA&T areas;
A comprehensive security plan.

Training

The RO provides comprehensive initial and annual training in biosafety, containment, medical surveillance and security procedures to individuals with access to agents and toxins.

Reporting

- Suspected loss or theft of select agents or toxins and changes in circumstances must be reported to the RO and the CDC or APHIS immediately upon discovery.
- The Principal Investigator must report all research-related accidents or illnesses to EH&S and the IBC. The IBC is responsible for reporting any significant problems with or violations of the Select Agent regulations and any significant research-related accidents or illnesses to NIH within 30 days. The RO must report problems with or violations of the Select Agent regulations and any research-related accidents or illnesses to the CDC immediately.
- **Post-exposure treatment must be started as soon as possible following an exposure incident.** If an exposure occurs, the individual should immediately go to Campus Health Service. If Campus Health is closed, follow-up care may be obtained at the nearest emergency room and reported to Campus Health Service and EH&S the next business day.

Recordkeeping

- The ASU Office for Research and Sponsored Projects Administration maintains records of registrations approved by the IBC.
- The Responsible Official must keep records for three years.

Technical Contacts

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