ASU FACT SHEET
Possession, Use, and Transfer of Select Agents and Toxins

Introduction

Biological Select Agents and Toxins (BSAT) are biological materials with the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products and whose possession, use, and transfer are regulated by the Department of Health and Human Services and the Department of Agriculture. ASU is required to collect and maintain information regarding the use or possession of BSAT anywhere on campus. Immediately contact the ASU Biosafety Officer if you currently possess or plan to acquire any of the listed agents or toxins. Failure to provide notice may result in civil and criminal liability for individuals and ASU. All work with BSAT at ASU must be approved by the Institutional Biosafety Committee (IBC).

Applicable ASU Policies

ACD 126 - Reference Check and Background Verification
EHS 112 - Biosafety and the Possession, Use, and Transfer of Select Agents and Toxins
EHS 114 - Biosafety Serum Storage Program
EHS 406 - Shipping and Receiving Hazardous Materials

ASU Guidelines

Biosafety Manual
Biological Hazardous Waste Handling Procedures
Laboratory-specific biosafety standard operating procedures (SOPs); EH&S has a template that may be used to create SOPs.

Regulations

Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH)
Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH)
Possession, Use, and Transfer of Select Agents and Toxins (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Parts 72 and 73)

Summary of Requirements

Either the CDC or APHIS approves participation in the Select Agent and Toxin Program. Individuals must be fingerprinted and complete the FD-961 form. IBC registration and approval of all BSAT work is required. The containment level for work with BSAT is determined by IBC based on a risk assessment, requirements listed in the federal select agent regulations, and recommendations in the BMBL and NIH Guidelines. Compliance is a condition for funding, regardless of the source. The Principal Investigator must complete and submit an IBC disclosure for all experiments involving BSAT.

Biosafety Training

ASU Biosafety Training must be taken prior to initial work with biohazardous materials and then at least every four years thereafter. More frequent training may be required if there are any significant findings during an inspection, after an accident or injury involving biohazards, when biosafety procedures or policies change, or after an adverse event in the laboratory. The ASU Biosafety Training is available through ASU Blackboard.
BSAT Training

The Responsible Official (RO) and Biological Safety Officer (BSO) provide initial and annual training in biosafety, biosecurity, containment, and incident response procedures to individuals with access to BSAT.

Reporting

Suspected theft, loss, or release of BSAT must be reported to the RO, BSO, and the CDC or APHIS immediately upon discovery. The Principal Investigator must immediately report all research-related accidents or illnesses to Biosafety & Biosecurity and the IBC. The IBC is responsible for reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to NIH within 30 days unless the IBC determines that a report has already been filed by the Principal Investigator.

Post-exposure treatment must be started as soon as possible following an exposure incident. If an exposure occurs, the individual should immediately go to ASU Health Service. If ASU Health is closed, care may be obtained at the nearest emergency room and reported to ASU Health Service and Biosafety & Biosecurity the next business day.

Records

The ASU Office for Research Integrity and Assurance maintains records of registrations approved by the IBC. Training records must be kept for 3 years. The RO must retain all other BSAT-related records for 3 years.