Title of SOP:	**General Use of Select Agents and Toxins SOP**	
SOP Originator:	Date Created:	Effective Date:
Name:	Name	Last edited Date:
EHS Reviewer:	Date Reviewed:	Document #:

PURPOSE:

The Select Agent and Toxin Use program outlines the registration procedures and responsibilities for individuals who work with select agents and/or select toxins. Portland State University and all individuals involved with select agent and toxin research are required to comply with the Federal Select Agent Program established by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS). Compliance is required under Federal Law; non-compliance can result in substantial penalties for both an individual and the University. All individuals must register with the University and possibly the Federal government prior to possessing any select agent or toxin.

SCOPE:

Portland State University's Select Agent and Toxin Use SOP is applicable to any employee of the University having access to a select agent or toxin. Access includes the ability to carry, use or manipulate an agent or toxin or the ability to gain entry into an area where select agents or toxins are used or stored.

APPLICABILITY:

Select Agents and Toxins:

Select agents and toxins are those biological agents and toxins listed in 42 CFR 73.3 and 73.4. These agents and toxins are federally regulated by the HHS and/or USDA and undergo biennial review. The list of select agents and toxins can be found on the National Select Agent Registry.

Genetic Elements, Recombinant and/or Synthetic Nucleic Acids, and Recombinant and Synthetic Organisms:

Recombinant and/or synthetic nucleic acids and organisms can also be subject to the regulations under the Federal Select Agent Program. These include:

- Nucleic acids that can produce infectious forms of any of the select agent viruses.
- Recombinant and/or synthetic nucleic acids that encode for the functional form(s) ofany select toxin if the nucleic acids can be expressed *in vivo* or *in vitro*, or are in a vectoror recombinant host genome and can be expressed *in vivo* or *in vitro*.
- Viruses, bacteria, fungi, and toxins listed above that have been genetically modified.

Restricted Experiments:

An individual may not conduct or possess products resulting from a restricted experiment with a select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary.

Restricted experiments are:

- Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.
- Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 <100 ng/kg body weight.

An individual must submit a written request and supporting scientific information to the CDC to apply for approval to conduct or possess products from a restricted experiment. A written decision granting or denying the request will be issued from the HHS Secretary.

Exclusions:

Select agents or toxins that are excluded from regulation include:

- Those agents or toxins that are in their naturally occurring environment, provided that it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Non-viable select agent organisms or non-functional toxins.
- Certain attenuated and vaccine strains of select agents and toxins. Please check the following link for the Notification of Excluded Attenuated Strains.
- Certain select toxins, under the control of an investigator, if the aggregate amount does not at any time exceed the amounts listed below in Table 1. (Note: the toxin quantities listed below are referred to as "Exempt" quantities throughout the remainder of this document. Those toxins whose aggregate amount exceeds that listed below are referred to as "Non-exempt" toxins.)

HHS Toxin	Amount
Abrin	1000 mg
Botulinum neurotoxins	1 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol (DAS)	10,000 mg
Ricin	1000 mg
Saxitoxin	500 mg
Staphylococcal enterotoxins (Subtypes A-E)	100 mg
T-2 toxin	10,000 mg
Tetrodoxin	500 mg

PROCEDURE:

Responsibilities:

Biosafety Officer

The Biosafety Officer (BSO) is an individual, designated by the University, with the authority and control to ensure compliance with the regulations in 42 CFR 73. The University has designated Scott Jaqua (5-5269). For more information on the Biosafety Program please visit the website.

Principal Investigator working with select agents or (non-exempt) toxins

A Principal Investigator (PI) working with select agents or (non-exempt) select toxins is responsible for the following:

- Contacting Scott Jaqua, BSO, and arranging to obtain CDC/FBI approval prior to any work with select agents or toxins.
- Receiving prior approval from the BSO and, the Federal Government for all transfers of select agents or toxins into or out of the facility.
- Adhering to proper procedures outlined in all applicable safety and security manuals.
- Maintaining a list of select agent approved staff.
- Apprising staff of the hazards associated with the select agent or toxin and ensuring staff are properly trained prior to working with the agent, including:
    - Laboratory specific training.
    - EHS general training (e.g., Bloodborne Pathogens, Basic Biosafety, Lab Chemical), if appropriate.
    - Animal Care and Use training, if appropriate.
- Preparing written Standard Operating Procedures (SOPs) for select agent or toxin research procedures and ensuring no research is conducted that is not outlined in the SOP.
- Apprising the BSO and any applicable committees of all changes in the research proposal, including:
    - Use of recombinant DNA or synthetic nucleic acids or recombinant organisms.
    - Changes in the select agent or toxin.
    - Changes in staff.
    - Use of animals.
- Maintaining a current inventory.

Principal Investigator working with exempt quantities of select toxins

A PI working with exempt quantities of select toxins is responsible for:

- Preparing written SOPs for toxin-involved research procedures.
- Providing initial lab-specific safety training to staff on toxin-involved processes, with updates as necessary. Ensure documentation of training is maintained. Training topics should include:
    - Toxin-associated hazards.
    - Engineering controls used to minimize exposure (e.g., fume hood use).
    - Personal protective equipment (PPE) to be used when handling the toxin.
    - Safe handling and storage.
    - Proper decontamination and disposal.
    - Administrative requirements (recordkeeping, inventory, security).
- Providing appropriate PPE (e.g., gloves, safety goggles, lab coat or disposable lab coat), completing the PPE hazard assessment written certification, and training all staff in t use of appropriate PPE. Note: if respirators are necessary, contact EHS at 5-4325 for required respirator use approval and compliance documentation.
- Ensuring proper use of the fume hood, biosafety cabinet, or glove box with toxin-associated procedures.
- Using accepted inactivation procedures prior to disposal of remaining toxin stock and/or empty containers (contact BSO for more info).
- Disposing of residual wastes, after inactivation, as follows:
    - Liquids: Free liquids less than a few milliliters can be disposed of in a red plastic biowaste tub, provided there is no other characteristic of the waste that makes it a hazardous waste, such as heavy metals, flammability, etc. Otherwise, free liquid (up to ~5ml) can be poured out on absorbent paper prior to placement in a red tub or can be absorbed/solidified with a material such as vermiculite. A chemical

waste pickup request for disposal should be submitted for any larger amounts of free liquid.
    - Stock vials and other materials: Deface container labeling. Collect in non-leaking container and place in a red plastic biowaste tub, with the same conditional statement as above.
- Ensuring proper storage/security. Items must be:
    - Stored with compatible materials within secondary containment; and
    - Provided one layer of physical security (e.g., toxin secured within a locked freezer or secured within a permanently fixed lockbox).
- Ensuring that each staff member who uses the toxin has received training and records any addition or removal in the inventory records, prior to initiating any research with a toxin.
- Maintaining a current inventory of toxins; the online chemical inventory system may be used for this purpose. In order to ensure that the exempt quantity limits are not inadvertently surpassed, inventories are to be promptly updated after every container of toxin is:
    - Acquired (by purchase/intra-campus transfer);
    - Depleted (by consumption /intra-campus transfer); or
    - Inactivated

Access to select agents and registration:

University registration procedures
All entities must register with the Federal Government in order to have access to select agents or (non-exempt) select toxins. An entity is any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

Individual person registration procedures
Each Individual must complete the following procedure to register with the Federal government.

- All PSU employees must contact Scott Jaqua, BSO.
- Federal law requires a user's registration be based at each facility in which select agents will be stored or use
- All individuals requesting access to select agents or select toxins above the exempted amount must complete a security risk assessment by the FBI and receive a registration approval number prior to gaining access to select agents. The PI and any staff listed in Section A on the Select Agent Internal Registration form will be contacted for fingerprinting and completion of the FBI FD-961 form.

 The registration process should be initiated as soon as possible as there are often significant time delays in receiving registration approval from the federal government.

 The RO or Laboratory Director will notify appropriate individuals when access to select agents has been authorized by the federal government and the SARC. Individuals will then be enrolled in the ongoing suitability assessment program as long as access to the agents is maintained.

ATTACHMENTS: