Simmons
UNIVERSITY

SELECT AGENTS AND TOXINS POLICY

1.0 INTRODUCTION

Select agents and toxins are a subset of biological agents and toxins that the United States (U.S.) Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. In March 2005, the HHS – Centers for Disease Control and Prevention (CDC) and USDA – Animal and Plant Health Inspection Service (APHIS) implemented the Bioterrorism Act by issuing the Select Agent Regulations, which consist of:

- 7 Code of Federal Regulations (CFR) Part 331
- 9 CFR Part 121
- 42 CFR Part 73

These regulations outline the requirements when working with select agents and/or toxins. Depending on the amount of the select agent and/or toxin, the requirements vary on a federal level. This program is overseen by the Federal Select Agent Program, which is comprised of representatives from HHS-CDC Division of Select Agents and Toxins and USDA- APHIS Agricultural Select Agent Program.

In addition to these regulations, since 1984, HHS – CDC has published the Biosafety in Microbiological and Biomedical Laboratories (BMBL) to provide a guideline for working with and containing infectious microorganisms and hazardous biological materials. The BMBL is known as the standard of care for biosafety practices and principles. It also provides guidelines when working with select agents and toxins.

On a local government level, the Boston Public Health Commission (BPHC) has regulations that require specific requirements when working with select agents and toxins. The regulations are as follows:

- Disease Surveillance and Reporting Regulation
- Biological Laboratory Regulations

At Simmons University (Simmons), the Institutional Biosafety Committee (IBC) requires that Simmons' laboratories working with select agents and/or toxins adhere to the requirements outlined in the regulations and guidelines summarized above and registered their work with them.

To review these regulations, guidelines and requirements, refer to the following links:

- Select Agents and Toxins: http://www.selectagents.gov/
- BMBL: http://www.cdc.gov/biosafety/ then type "BMBL" in search engine space
- BPHC: http://www.bphc.org/boardofhealth/regulations/Pages/Biological-Laboratory-Regulation.aspx

2.0 SCOPE AND PURPOSE

To meet the regulatory and guideline requirements for select agents and/or toxins, Simmons' Environmental Health & Safety (EH&S) Office has prepared this Standard Operating Procedure (SOP) to assist Simmons' laboratories when investigating whether or not to use select agents and/or toxins in their research and to provide guidelines and policies on how to ensure regulatory compliance when working with select agents and/or toxins in their laboratories.

3.0 RESPONSIBILITIES

In order to ensure compliance with Simmons' obligation under the select agents and toxins' regulations, registrations, and guidelines; it is important that affected faculty, laboratory staff, and department administrators understand their responsibilities associated with ordering, preparing, handling, using, and disposing of select agents and/or toxins.

Depending on the amount, characteristic, and/or use of the select agent and/or toxin, a Responsible Official (RO) may be required for the laboratory and/or school. The RO is the individual designated by the registered entity with the authority and responsibility to act on behalf of the entity to ensure compliance with the select agent regulations. There can be only one RO at a registered entity at any given time. In the absence of the RO, a previously appointed and approved alternate Responsible Official (ARO) may assume the RO's responsibility and has the authority to act on behalf of the registered entity. The RO for Simmons is the Chair of the Biology Department.

The RO is permitted to authorize a person to work with a select agent and toxin as long as the work does not required additional administrative and engineering controls. The RO will notify the Institutional Biosafety Committee (IBC) via email when there is a change in the select and toxin program. If the select agent and toxin work requires a change in the administrative and/or engineering controls, then the IBC will meet to review the work.

This section also outlines the responsibilities for the laboratory staff and administrative departments, which assist departments with their select agents and/or toxins to ensure compliance with applicable regulations, registrations, and guidelines.

3.1 Faculty, Principal Investigators, Adjuncts

Faculty, Principal investigators (PIs) and Adjuncts will be responsible for:

- Contacting the Biological Safety Officer (BSO) within the Simmons about their intent to use select agents and/or toxins in their laboratory **prior to ordering** the select agent and/or toxin.
- Managing the ordering, delivery, inventory, use, and disposal of select agents and/or toxins.
- Ensuring that select agents and/or toxins are registered with CDC/APHIs, BPHC, and/or the Institutional Biosafety Committee as applicable.
- Maintaining and using select agents and/or toxins in accordance with their applicable registration(s), the Institutional Biosafety Committee approval letter(s), and policies, procedures, and SOPs including this one.
- Developing a laboratory-specific SOP for select agents and/or toxins being used in their laboratory.
- Restricted access to the select agents and/or toxins only to users that are authorized to use select agents and/or toxins.
- Ensuring usage logs, purchase orders, and inventories are properly kept.
- Contacting the corresponding Simmons EH&S Office at 617-521-2525 to inform them that you need to dispose of select agents and/or toxins.
- Notifying the appropriate Simmons department(s) and/or regulatory agencies about unauthorized or suspicious persons; loss or compromise of keys, passwords, or combinations; loss or theft of select agents and/or toxins; and alteration of inventory records.

In the event that the Faculty, PIs or Adjuncts are on leave or are otherwise absent, they may designate another appropriate person within their laboratory to assume these responsibilities.

3.2 Laboratory Staff

Affected laboratory staff will be responsible to adhering to the requirements outlined in tthe Institutional Biosafety Committee approval letter, and the policies and procedures outlined in this SOP. At a minimum, affected laboratory staff will:

- Complete a Security Risk Assessment, if required to do so.
- Complete a training program about select agents and /or toxins.
- Report to their PI about unauthorized or suspicious persons; loss or compromise of keys, passwords, or combinations; loss or theft of select agents and/or toxins; and alteration of inventory records.

Laboratory staff authorized to work in areas where select agents and/or toxins are being stored and/or used will be known as Authorized Users.

3.3 Department Chairs

Department chairs will assist faculty and laboratory staff in complying with the requirements provided in applicable registration(s), their approval letter(s), and policies, procedures, and SOPs including this one.

3.4 RO

The registered entity must not only assign the RO the responsibility to ensure compliance with the select agent regulations, the entity must also ensure that it delegates to the RO sufficient authority to speak and act on behalf of the entity. A registered entity which fails to vest in its RO sufficient authority to ensure compliance with all of the requirements of the select agent regulations has failed in one of its primary responsibilities. The core responsibilities of and criteria to be the RO are that (s)he:

- Pass a security risk assessment (SRA) conducted by the Federal Bureau of Investigation (FBI), Criminal Justice Information Services (CJIS) and be approved by the Federal Select Agent Program.
- Is familiar with the select agent regulations to the extent that the RO can ensure that his or her entity is compliant with all of the requirements of the select agent regulations.
- Ensures compliance with the select agent regulations.
- Ensures that annual inspections are conducted for each laboratory and all other registered areas where select agents or toxins are stored or used in order to determine compliance with the requirements of the select agent regulations. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.
- Must have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and be able respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan.

3.5 Simmons' EH&S Office

The Simmons EH&S Office will:

- Conduct annual inspections of laboratories working with select agents and/or toxins.
- Provide inspection summary reports including corrective action recommendations to the PI, laboratory safety contact, department administrator, and/or RO/ARO.
- Provide informational materials to assist PIs, laboratory staff, department administrators, and ROs/AROs to ensure compliance with applicable regulations, registrations, the PI's COMS approval letter, and the policies and procedures outlined in this SOP.
- Assist with risk assessments for select agent(s) and/or toxin(s) including the SRA.
- Assist with the disposal of select agents and/or toxins and providing options for proper disposal.

3.6 Public Safety

Public Safety will assess the laboratory in meeting the physical security requirements when working with select agents and/or toxins and assist the laboratory in meeting these requirements. Examples of physical security include locked doors, personalized key cards, pin numbers, and/or biometrics for access. In addition, the Security Office or Department will assist in investigations

In addition, they will help enforce this policy in laboratories working with select agents and/or toxins and support investigations regarding theft or loss of select agents and/or toxins, and damaged or unknown packages.

4.0 REGISTRATIONS

The registration process is dependent on the amount, characteristic, and/or use of select agent and /or toxin being proposed for the research and whether or not the exclusions provided in the following regulations apply to the research:

- 7 CFR Part 331
- 9 CFR Part 121
- 42 CFR Part 73

All Simmons laboratories working with select agents and/or toxins are required to complete Institutional Biosafety Committee registration.

NOTE: PIs or designees should contact the IBC about their intent to use select agents and/or toxins to ensure the proper registrations are obtained prior to ordering the select agents and/or toxins.

4.1 Non-Excluded

Laboratories proposing to work with select agents and/or toxins, which are not excluded from the federal regulations provided above, must apply for a certificate of registration to the HHS/CDC or USDA/APHIS not both. **It is illegal to possess and/or use select agents and/or toxins, which are not excluded, without registering with the appropriate agency first.** Below are the guidelines to determine where to submit the federal registration:

- HHS select agents and toxins (see 42 CFR 73.3) – Submit the completed form to CDC.
- USDA Veterinary Services select agents and toxins and/or "USDA Plant Protection and Quarantine select agents and toxins (see 9 CFR 121.3, 7 CFR 331.3) – Submit the completed form to APHIS.
- Any combination of "HHS select agents and toxins," "USDA VS select agents and toxins," "USDA PPQ select agents and toxins," and "Overlap select agents and toxins" (see 42 CFR 73.4 and 9 CFR 121.4) – Submit the completed form to either CDC or APHIS, but not both.

In addition, the laboratory will be required to submit a permit application to BPHC depending on the location(s) of the laboratory.

4.2 Excluded

If the amount, characteristic, and/or use of the select agent and/or toxin meet(s) the definition of exclusion by the federal regulations, then the laboratory will be only required to register with the IBC and BPHC.

One exclusion example: The amount of the select agent and/or toxin doesn't exceed a certain amount. Refer to Table 1, which provides the excluded amounts for select agents and/or toxins commonly used at Simmons as provided in 42 CFR 73.3.

Table 1 – Excluded Amounts	
Select Agent or Toxin	**Excluded Amount (as viewed on 08/19/14)**
Saxitoxin	≤ 100 mg
Tetrodotoxin	≤ 100 mg

5.0 Security and Storage

"*One of the fundamental elements of the select agent regulations is to keep select agents and toxins out of the possession of individuals who might intend to misuse them. The Federal Select Agent Program works closely with Department of Justice's (DOJ) Federal Bureau of Investigation (FBI), Criminal Justice Information Service (CJIS) to identify those individuals who are prohibited from access to select agents and toxins based on the restrictions identified in the U.S. Patriot Act".* (Source viewed on August 19, 2014: http://www.selectagents.gov/sra.html)

An inventory control system should be implemented to account for the select agent and/or toxin upon entry into a laboratory, during use, and upon disposal. See Section XII for details.

During the Security Plan process, the following should be reviewed:

- Physical security
- Data and informational technology system security
- Security policies for personnel
- Policies for accessing select agent areas
- Specimen accountability
- Receipt of select agents into the laboratory
- Transfers or shipping of select agents from the laboratory
- Emergency Response Plan
- Reporting of incidents, injuries, and breaches

5.1 Non-Excluded

To accomplish this task, laboratories working with non-excluded select agents and/or toxins are required to complete SRAs (individual and site-specific) and a Security Plan.

For each individual listed in the certificate of registration application, a SRA form must be completed and submitted to the FBI. Individuals approved by the FBI will be known as "Authorized Users".

The site-specific risk assessment includes:

- Agent-specific risk assessment
- Threat assessment
- Vulnerability assessment
- Graded protection determination

Please refer to the Security Plan for your laboratory for details.

5.2 Excluded

PI or designee must ensure that the following requirements are met for select agents and/or toxins, which met the one of the criteria for exclusion.

- Consolidate work areas, if possible.
- Keep secure under lock and key.

- Ensure access is restricted to laboratory members, who are authorized to use the select agent(s) and/or toxin(s) (a.k.a., Authorized Users) and to perform work in this area.
- Lock select agent areas when unoccupied.

5.3 Storage

Containers of select agents and /or toxins and their aliquots should be stored in locked cabinets, locked refrigerators, or safes in locations when they are not in direct view of a laboratory worker, who is an Authorized User. When storing in a refrigerator or freezer, use lock boxes. Access is a key element in providing security for select agents and/or toxins.

5.4 Designated Areas

Experiments using select agents and/or toxins should be done only in designated rooms with controlled access and at pre-determined bench top areas. When select agents and/or toxins are in use, a sign stating "TOXINS IN USE – AUTHORIZED PERSONNEL ONLY" should be posted at the entrance to the area or the bench top area.

5.5 Visitors

Visitors include personnel from universities, contractors, students, research fellows, visiting scientists, laboratory visitors, trades professionals, delivery personnel, etc. who, due to the duration of stay or nature of the work performed on site, is not provided with regular access to the laboratory using select agents and/or toxins. Visitors are escorted at all times in restricted (non-public) areas by an individual who has a complete and approved background investigation, access authorization, and a need-to-know. Visitors are expected to wear a visitor badge, sign all visitor logs, remain with their escort, and follow all facility policies and procedures, while in the laboratory.

6.0 PURCHASING AND TRANSFERS

Once the PI or designee receives the appropriate registrations (See Section 4.0), then the PI or designee is able to order the select agents and/or toxins. The purchase order or other paperwork associated with purchasing the select agents and/or toxins should be maintained by the laboratory.

If the PI or designee requires that a non-excluded select agent and/or toxin be transferred to another PI or designee, then the following conditions must be met:

- The sender and recipient must be registered to possess, use, or transfer the select agent and/or toxin.
- The transfer must meet the requirements specified the section entitled "Transfers" in 7 CFR 331, 9 CFR 121, and 42 CFR 73.
- If transferring outside the U.S., then the shipment must adhere to the International Air Transport Association (IATA) Dangerous Goods Regulations (DGRs) and/or the country's import requirements, if applicable.
- The appropriate paperwork must be submitted to the APHIS/CDC for transfer authorization prior to the transfer.
- The person conducting the packaging is an individual approved by the HHS Secretary or Administrator.
- The sender/recipient must be trained in and comply with applicable shipping laws and regulations including but not limited to U.S. Department of Transportation (DOT) Hazardous Materials Regulations and IATA DGRs.
- The recipient is an individual approved by the HHS Secretary or Administrator to have access to the select agent and/or toxin.
- The recipient must submit a completed APHIS/CDC form within two business days of receipt of the select agent and/or toxin.

- The recipient must notify APHIS or CDC if the select agent and/or toxin has not been received within 48 hours after the expected delivery time, or if the package containing the select agent and/or toxin has been damaged to the extent that a release of the select agent and/or toxin may have occurred.
- An authorization for a transfer shall be valid only 30 calendar days after issuance unless the authorization becomes null and void if any facts supporting the authorization change.

If the select agent and/or toxin is excluded, then the PI or designee must:

- Transfer the amount only after due diligence and documents demonstrate that the recipient has a requirement in a peaceful purpose (e.g., research, **prophylactic)** to handle or use the select agent and/or toxin.
- Report to CDC if (s)he becomes aware of a known or suspected violation of applicable laws and regulations associated with the transfer.

Below are some guidelines about transferring select agents and/or toxins.

- Package, label, and transport select agents and toxins in accordance with applicable shipping laws and regulations including but not limited to DOT Hazardous Materials Regulations and IATA DGRs.
- Ensure required permits (e.g., CDC, USDA, DOT, IATA, Department of Commerce) are obtained before select agents and/or toxins are prepared for transport.
- Decontaminate contaminated and possible contaminated materials before they leave the laboratory area.
- Avoid hand-carrying select agents and/or toxins when transferring them to other external facilities located nearby.

7.0 RECEIVING SELECT AGENTS AND/OR TOXINS

When receiving select agents and/or toxins, the following are recommended to maximize safety and minimize security hazards:

- Ensure a person trained and authorized receives the select agent and/or toxin package.
- If a package is damaged or is unknown, notify the PUBLIC SAFETY.
- Use engineering controls (e.g., chemical fume hoods, biosafety cabinets) when opening packages containing specimens, bacterial or virus isolates, or toxins.

8.0 RISK ASSESSMENT AND LAB-SPECIFIC SOP

A risk assessment should be performed for each experiment involving a select agent and/or toxin unless the experiments are the same. The IBC recommends that a member of their staff assist the laboratory with this assessment. If the experiment process and/or hazard(s) associated with the experiment change, then another risk assessment should be performed. Appendix A provides technical information associated with select agents and toxins commonly used in a laboratory setting at Simmons. Please use this document to conduct this risk assessment and help with the development of the Lab-Specific SOP.

This assessment should:

- Be used to develop a Lab SOP for select agent and/or toxin use in a laboratory.
- Review the Safety Data Sheets (SDSs) for the select agents, toxins, biological materials, and/or hazardous chemicals being used in the experiment.
- Cover from when the select agent and/or toxin enter the laboratory until it is disposed of, consumed in an experiment, rendered inactive by other means, and/or destroyed.
- Review animal work with the select agent and/or toxin, if applicable, and
- Be documented and maintained by the laboratory.

Based on the risk assessment, a Lab SOP should be developed by the PI or designee and consist of the following, at a minimum. This Lab SOP should be reviewed by a representative from the Simmons EH&S Office prior to implementation.

- **Title of Procedure** - Should indicate the specific chemical, task or experiment for which it was written.
- **Description -** Include a general description of what activities are covered under this procedure. List any specific examples of when the procedure must be implemented or any exemptions when the procedure is not required. If authorization for this procedure is limited to designated staff, that fact should be noted in this section.
- **Procedure –** Enumerate or list the safety steps to be followed in performing the procedure. The steps should be sufficiently detailed, and should include any prohibited activities or any potentially dangerous conditions.
- **Potential Hazards** – Complete the hazard description table for each of the principal materials utilized in this procedure. SDSs, when available, should be obtained and attached to the procedures template. Many operations can result in secondary materials or hazardous by-products. A discussion of these materials should be included in this section if they represent a significant, but different hazard than the other materials.
- **Engineering/Ventilation Controls** – Identify the engineering controls, such as lab chemical fume hoods, implemented to minimize exposures to hazardous materials and processes.
- **Additional Precautions** – Indicate and describe any management approvals, medical surveillance, training or specific permits that must be obtained in order to conduct this procedure. Questions regarding applicability of these categories should be directed to the lab safety representative/officer or EH&S.
- **Safety References** – Additional safety information, including SDSs and other information. Add any lab-specific information, as appropriate.
- **Waste Disposal** – Refer to Section XI of this SOP. As appropriate, list any additional equipment, supplies or procedures that are unique to the referenced materials or operations.
- **Emergency Procedures** – List any additional emergency equipment, supplies or procedures that are unique to the referenced materials or operations.

9.0 TRAINING

The PI or designee must ensure that laboratory members working with select agents and/or toxins are trained so they:

- Are comfortable performing the experiment;
- Know the hazard(s) associated with the experiment and with each select agent and/or toxin used in the experiment;
- Are familiar with the Lab SOP;
- Understand how to use the PPE and engineering control associated with the experiment;
- Know how to decontaminate, inactivate, destroy, and dispose of the select agent and/or toxin;
- Report any theft, suspected theft, loss, release, and exposure associated with select agents and/or toxins in a timely manner;
- Notify the appropriate authorities when an unauthorized person is in the designated area; and
- Know the procedures when there is an emergency (e.g., exposure, spill).

This training should be documented by the PI or designee. Inexperienced staff requires direct oversight until they are able to demonstrate that they know the proper techniques to perform the experiment.

10.0 LABORATORY USE GUIDELINES

The requirements for work with select agents and/or toxins will be outlined in the risk assessment performed by BSO and IBC, in their approval letter, and the Lab SOP. Laboratory members working with the select agents and/or toxins must follow the requirements outlined in this SOP, the IBC letter and the Lab SOP.

Depending on the experiment, the laboratory use guidelines will vary. These guidelines are implemented to prevent an exposure to a select agent and/or toxin, prevent an accidental spill, and remove contamination when working with select agents and/or toxins. Below are some guidelines:

- Eliminate or minimize work with dry select agent and/or toxin. If working with dry select agent and/or toxin, then:
    - Use “Static-free” disposable gloves if the select agent and/or toxin is/are subject to spread by electrostatic dispersal.
    - Inject the solution into the container via the septum.
    - Do not pour the dry select agent and/or toxin out of the container.
- Order select agent and/or toxin in liquid form.
- Transport select agent and/or toxin solutions in leak/spill-proof secondary containers.
- Select the appropriate personal protective equipment (PPE) based on the potential exposure to hazards during the experiment.
- Don the appropriate PPE prior to the experiment and wear throughout the experiment until the destruction and/or disposal activities are done.
- Select gloves that are impervious to the select agent and toxin including the diluents or solvents used to make aliquots or working solutions.
- If there is a splash or droplet hazard, wear safety glasses and disposable respirator or a face shield. If using a disposable respirator, then contact the Simmons EH&S Office at 617-521-2525 to determine whether or not additional requirements apply to the use of this disposable respirator.
- Conduct work in designated areas of the engineering control (e.g., chemical fume hood or biosafety cabinet).

- Ensure that the engineering control is functioning properly (e.g., providing inward airflow) and has the appropriate filters (e.g., **High-efficiency particulate air** [HEPA]), if applicable, prior to initiating work.
- While a select agent or toxin is being used in an engineering control, post a sign on the engineering control indicating that "TOXINS IN USE – DO NOT USE UNLESS AUTHORIZED TO USE". This sign should remain on the engineering control until the engineering control is properly decontaminated.
- Eliminate the possibility of generating toxin aerosols.
- Reduce or eliminate the use of sharps (e.g., needles, glass Pasteur pipettes) and glassware to minimize the risk of cuts, injury, and/or exposure.
- Enclose gas chromatography columns under pressure with a plastic water jacket or other secondary container.
- Ensure that vacuum lines are protected with the appropriate filter (e.g., hydrophobic, HEPA) to prevent select agents or toxins from entering the vacuum line.
- Centrifuging select agents or toxins and/or their aliquots should be performed using sealed, thick-walled tubes in safety centrifuge cups or sealed rotors.
- Open equipment used with select agents and/or toxins in the appropriate engineering control.
- Routine clean equipment prior to and after using it with select agents and/or toxins.
- Decontaminate secondary containers, bench tops, work surfaces within the engineering control, and/or the interior of the engineering control prior to and after each use of select agent or toxin.
- Dispose, destroy, or deactivate the select agents, toxins, and/or aliquots containing select agents and/or toxins once the laboratory is done using them. Refer to Section XI for details.

11.0 DECONTAMINATION, INACTIVATION, DESTRUCTION, AND DISPOSAL

Once the laboratory is done using the select agent and/or toxin, the remaining select agent and/or toxin and aliquots containing the select agent and/or toxin must be inactivated, destroyed, and/or disposed of. In addition, the equipment, secondary containers, bench tops, work surfaces within the engineering control, and/or the interior of the engineering control should be decontaminated prior to and after each use of select agent or toxin. The methods for decontamination, inactivation, destruction, and disposal are provided below.

11.1 Decontamination and Inactivation

The method for decontamination and/or inactivation is dependent on several conditions including but not limited to: pH, temperature, ionic strength, and whether or the select agent and/or toxin is susceptible to heating or the specific chemical. Inactivation procedures should be validated using specific toxin bioassays before it can be assumed that the procedure is 100% effective. Refer to Table 2 for a list of physical and chemical inactivation methods for select agents and/or toxins commonly used in Simmons laboratories.

Table 2 – Physical and Chemical Inactivation Methods Select Agents and/or Toxins					
Select Agent/Toxin	**Autoclave** (1 hour at 121°C liquid cycle slow exhaust)	**NaOCl**	**NaOH**	**NaOCl + NaOH**	**Comments**
Saxitoxin	No	≥ 0.1%	ND	> 0.25% + 0.25 N	
Tetrodotoxin	No	≥ 0.5%	ND	> 0.25% + 0.25 N	

NOTES:
ND – Not Determined
NaOCl – Sodium hypochlorite
NaOH – Sodium hydroxide

1. Autoclaving is not effective with low molecular weight (LMW) toxins (e.g., T-2 mycotoxin). All burnable waste from LMW toxins should be incinerated at temperatures in excess of 815°C.
2. Allow for at least 30 minutes for the chemicals to inactivate the select agent and/or toxin.
3. Exposure for 30 minutes to 1.0% NaOCl is an effective procedure for the laboratory (working solutions, equipment, animal cages, working area, spills) for the inactivation of saxitoxin or tetrodotoxin.

11.2 Destruction and Disposal

Prior to destroying select agents and/or toxins or aliquots of select agents and/or toxins, please contact the Simmons EH&S Office at 617-521-2525 **at least seven (7) working days in advance**. The reason for advance notification is that depending on the select agent and/or toxin the Simmons EH&S Office may need to notify and/or obtain approval from CFC or APHIS of the proposed destruction. Once the destruction is approved, the Simmons EH&S Office will notify the PI or designee.

Chemical Inactivation and Disposal

The following procedure is recommended for chemical inactivation for destruction.

1. Select the appropriate PPE based on the potential exposure to hazards during the destruction. Refer to your Laboratory's PPE Assessment for details.
2. Don the appropriate PPE prior to the destruction process and wear throughout the destruction process.
3. Line the inside of the engineering control (e.g., chemical fume hood, biosafety cabinet) with plastic-backed absorbent pads (e.g., Chux™).
4. Prepare a fresh solution of the chemical inactivation solution and transfer the solution to the working surface of the engineering control. Refer to Table 2 for details.
5. Obtain secondary plastic containers with sealable lids and place them on the working surface in the engineering control.
6. Transfer containers containing select agents and/or toxins to the working surface within the engineering control. **NOTE:** Use a secondary containment lined with an absorbent material to transfer the containers.
7. Remove the containers and place them onto the absorbent pads within the engineering control.
8. If the select agent and/or toxin is/are in powder form, then dissolve in a solution through the septum. **NOTE:** Do not open the container.
9. Once the select agent and/or toxin is in solution form or for a select agent and/or toxin already in solution, open the container of select agent and/or toxin.
10. Place the open container of select agent and/or toxin into the secondary plastic container with sealable lid.
11. Carefully add the amount of chemical inactivating solution to the select agent and/or toxin.
12. Close the sash of the engineering control.

13. Post a sign "TOXINS IN USE – DO NOT USE UNLESS AUTHORIZED TO USE" on the engineering control.
14. Wait 30 minutes to ensure that the chemical inactivates the select agent and/or toxin.
15. Remove sign.
16. Replace the cap on the primary select agent and/or toxin container.
17. Place and secure the lid on the secondary plastic container.
18. Document the destruction of the select agent and/or toxin in laboratory select agent and/or toxin inventory log book.
19. Label the secondary plastic container with a completed hazardous waste label. Use the words "Inactivated/Denatured (TOXIN NAME)" for the chemical name.
20. Place the labeled secondary plastic container into your laboratory's Satellite Accumulation Area and contact the EH&S Office at 617-521-2525 for disposal.

Physical Destruction and Disposal

Please follow this procedure for physical destruction via an autoclave:

REMINDER: Autoclaving is not effective with LMW toxins (e.g., T-2 mycotoxin).

1. Select the appropriate PPE based on the potential exposure to hazards during the destruction. Refer to your Laboratory's PPE Assessment for details.
2. Don the appropriate PPE prior to the destruction process and wear throughout the destruction process.
3. Line the inside of the engineering control (e.g., chemical fume hood, biosafety cabinet) with plastic-backed absorbent pads (e.g., Chux™).
4. Transfer containers containing select agents and/or toxins to the working surface within the engineering control. **NOTE:** Use a secondary containment lined with an absorbent material to transfer the containers.
5. Loosen the cap of the primary select agent and/or toxin container to allow steam penetration.
6. Place the primary container into a biohazard sharps container.
7. Place sharps container into a pan used for autoclaving.
8. Autoclave for 1 hour at 121°C on liquid cycle (slow exhaust).
9. Document the destruction of the select agent and/or toxin in laboratory select agent and/or toxin inventory log book.
10. After autoclaving, allow time for the materials to cool before handling.
11. Discard the sharps container into a biohazard waste container lined with a red biohazard bag.

12.0 RECORDKEEPING

Each laboratory is required to keep track of each select agent and/or toxin including aliquots and working solutions using an inventory log. On a periodic basis (at a minimum **quarterly**), the PI or designee will conduct an audit of the inventory to ensure that the inventory logs correspond to the actual inventory. If there is a discrepancy, the PI or designee will notify the RO/ARO (if applicable), the PI (if (s)he is the designee), the department administrator and Public Safety.

Testing, diagnostic, and clinical samples are not controlled as part of the inventory log process. However, when the isolates have been identified in a clinical or diagnostic material as a select agent or toxin, and those isolates are kept for future use, the isolates are added to the inventory as soon as they are stored.

The inventory log may be in the form of an electronic database (such as Microsoft (MS) Access or SQL Server), spreadsheet files (such as MS Excel), or handwritten in logbooks. Only Authorized Users will have access to this inventory log book. Laboratories are required to maintain inventory logs for at a minimum of three years and must be promptly available upon request.

The log should have the following information:

- Name of select agent and/or toxin
- Characteristics (e.g., GenBank Accession number, strain designation)
- Location (e.g., Building, Room, and Freezer #)
- Use (e.g., Biomedical, Medical Research, Clinical)
- Lab Protocol Numbers, if applicable
- External and Internal Transfers
    - Sender/Receiver
    - Transfer Date
    - Number of containers, vials, tubes, etc.
    - Amount per container, vial, tube, etc.
    - Units
- A written explanation of any discrepancies
- Destruction
    - Method of destruction (e.g., autoclave, chemical inactivation)
    - Procedure used (Refer to Section XI for details)
    - Amount
    - Units
    - Date
    - Name of person who performed the destruction
    - Location of destruction (e.g., Building, Room, and Engineering Control Identification #)
    - Name(s) of witness(es)
- Theft or Loss
    - Amount
    - Units
    - Date
    - Which departments were notified and when (date and time)

In addition to an inventory of the select agents and/or toxins, the PI or designee must maintain:

- A list of individuals that have been granted access approval by the HHS Secretary or Administrator (a.k.a. Authorized Users).
- Information about all entries into areas containing select agents and/or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry.

13.0 REPORTING REQUIREMENTS

Simmons is required by regulation (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) to notify APHIS or CDC immediately upon discovery of a theft (unauthorized removal of select agent or toxin), loss (failure to account for select agent or toxin), or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent and toxin. This notification may be accomplished via telephone, facsimile, or email.

After the initial reporting, this form (APHIS/CDC Form 3) must be sent to APHIS or CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins. For theft or loss of select agents or toxins, Simmons must notify the appropriate local, state, or federal law enforcement agencies. For release of or an exposure to select agents or toxins, Simmons may also be required to notify the appropriate local, state, and federal health agencies.

13.1 Theft, Suspected Theft, or Loss

Thefts, suspected thefts, or other losses of select agents and/or toxins must be reported immediately to notify the RO/ARO (if applicable), the PI (if (s)he is the designee), the department administrator and PUBLIC SAFETY. The following information must be provided in the notification:

- The name of the select agent or toxin and any identifying information (e.g., strain)
- An estimate of the quantity lost or stolen
- An estimate of the time during which the theft or loss occurred
- The location (e.g., Building, Room, and Freezer #) for which the theft or loss occurred
- The list of state and federal agencies reported, or intends to report the theft or loss

13.2 Release of or Exposure to a Select Agent and/or Toxin

A release of or exposure to a select agent and/or toxin must be reported immediately to notify the RO/ARO (if applicable), the PI (if (s)he is the designee), the department administrator and PUBLIC SAFETY. The following information must be provided in the notification:

- The name of the select agent or toxin and any identifying information (e.g., strain)
- An estimate of the quantity released
- The time and duration of the release
- The environment into which the release occurred (e.g., in the engineering control, in building or outside building)
- The location (e.g., Building, Room) from which the release occurred
- The number of individuals potentially exposed
- Actions taken to respond to the release
- Hazard posed by the release

13.3 Unauthorized Person

Any unauthorized person, who gains access to select agents and/or toxins for the purpose of diversion or theft, may be reported to the PUBLIC SAFETY and may be subject to the disciplinary policies of Simmons.

14.0 EMERGENCY RESPONSE

Emergencies involving select agents and/or toxins may involve but is not limited to: spills, fire and evacuation, personal exposure or injury, first aid, medical emergency, power failure, ventilation failure, and natural disasters. Below are additional guidelines specific to select agents and/or toxins.

- Spill Response
  1. Notify Simmons Public Safety at 617-521-1111.
  2. Use the appropriate decontamination, inactivation, destruction, and/or disposal method(s) as outlined in Section 9.0.
- Fire and Evacuation – If you can do so safely, close, secure, and/or cover the select agent and/or toxin or containers of select agents and/or toxins before evacuating.
- Personal Exposure or Injury, First Aid, and Medical Emergency
  1. Immediately remove the patient/victim from the source, if it can be done safely.

2. Table 3 provides medical emergency response initial steps for select agents and/or toxins used in the laboratory setting at Simmons. If a toxoid or vaccine is available, then please have it available in your laboratory.
3. After initial steps, seek medical attention immediately.

Table 3 – Medical Emergency Response Initial Steps
Select Agents and/or Toxins

Select Agent/Toxin	Toxoid/Vaccine	Eye	Ingestion	Inhalation	Skin
Saxitoxin	None	Flush with tepid water for 15 minutes	ND	Assess situation; if difficulty breathing, administer oxygen, administer CPR using a barrier, if trained and able to do safely	If you able to do safely, remove clothing down to undergarments and place in biohazard waste bag; Wash and rinse the contaminated skin using soap and water; Be careful not to break the skin; Cover all wounds; Cover with blanket or another item to prevent shock and loss of body heat.
Tetrodotoxin	None	ND	Do not induce vomiting	ND	

NOTES:
CPR – Cardiopulmonary resuscitation
ND – Not Determined

- Power or Ventilation Failure and Natural Disasters
  - Stop work.
  - If you can do so safely:
    - Close, secure, and/or cover the select agent and/or toxin or containers of select agents and/or toxins.
    - Transfer containers of select agents or toxins to their secure storage location.
    - If the storage is within an engineering control (e.g., chemical fume hood, biosafety cabinet), lower the sash and post a sign that "TOXINS – DO NOT USE UNLESS AUTHORIZED TO USE".

15.0 REFERENCES

The following documents were used and reviewed during the development of this SOP:

- 7 CFR Part 331 – *Possession, Use, and Transfer of Select Agents and Toxins,* current as of September 30, 2013
- 9 CFR Part 121 – *Select Agents and Toxins,* current as of September 30, 2013
- 42 CFR Part 73 – *Possession, Use, and Transfer of Select Agents and Toxins,* current as of September 30, 2013
- HHS – CDC/NIH, HHS Publication Number: 21-1112, *Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition,* dated December 2009
- CDC, Division of Select Agents and Toxins, APHIS, Agriculture Select Agent Program, *Guidance on the Inventory of Select Agents and Toxins*, dated March 14, 2013

- John Hopkins Safety Manual – Policy Number HSE 505, *Acquisition and Use of Select Agents & Toxins*, dated September 20, 2013
- National Select Agent Registry, *Security Risk Assessments*, dated March 25, 2013
- HHS – CDC, Division of Select Agents and Toxins/USDA – APHIS, Agriculture Select Agent Program, *Select Agents and Toxins Security Information Document,* dated March 8, 2007
- University of Pennsylvania, *Destruction of Select Agents Procedures,* dated November 9, 2009
- The University of Iowa, *Toxin Inactivation Information,* no date provided on document
- CDC, *Guide to Developing an Incident Response Plan* presentation, no date provided on presentation
- CDC, Morbidity and Mortality Weekly Report, December 6, 2002, Article entitled "*Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents"*
- Simmons University, *Controlled Substance Researchers' Guide,* dated August 7, 2013
- CDC Emergency Response Card for Tetrodotoxin, viewed October 17, 2013

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APPENDIX A – TECHNICAL INFORMATION FOR COMMON SELECT AGENTS AND TOXINS USED IN SIMMONS LABORATORIES (ALPHABETICAL ORDER)

SAXITOXIN

- Chemical properties: Non-protein, Small molecular weight, Binds to ion channels, Marine toxins
- Mechanism of action: Binds to the sodium channel of the nerve preventing the passage of sodium ions through the cell membrane and therefore blocks passage of the nerve impulse.
- Routes of Transmission
    - Inhalation
    - Injection
    - Ingestion
- Signs and Symptoms
    - Onset: *Almost immediate. Exposure by inhalation leads to extremely rapid development of symptoms with death occurring within minutes if not treated.*
    - Tingling
    - Numbness
    - Weakness
    - Limp paralysis

NOTE: Symptoms can be confused with other poisonings, including Botulism, Ciguatera poisoning, Gastroenteritis, Insecticide poisoning

- Toxoid/vaccine available: No
- Toxicity (mg/kg)
    - Intravenous: 3.9 (mouse)
    - Intraperitoneal: 10 (mouse)
    - Oral: 263 (mouse)
    - Inhalation: <2 (in hamsters)

TETRODOTOXIN (TTX)

- Chemical properties: Non-protein, Small molecular weight, Binds to ion channels, Marine toxins
- Mechanism of action: Binds to the sodium channel of the nerve preventing the passage of sodium ions through the cell membrane and therefore of the nerve impulse.
- Routes of Transmission
    - Ingestion, primary route of transmission, typically from consuming Pufferfish
    - Inhalation
- Routes of Transmission (Laboratory)
    - Cut or injury with a contaminated sharp
    - Skin exposure
    - Splash to face, mouth, or eyes
- Signs and Symptoms
    - Onset: *Ranges from 20 minutes to 3 hours*
    - Tingling,
    - Numbness
    - Weakness
    - Lightheadedness
    - Limp paralysis leading to dyspnea (shortness of breath)
    - Cyanosis,
    - Cardiac arrhythmia
    - **Death**
- Toxoid/vaccine available: No
- Toxicity (milligram/kilogram [mg/kg])
    - Intravenous: 8.7(mouse)
    - Intraperitoneal: 8-10 (mouse)
    - Subcutaneous: 11.5 (mouse)