This guideline was prepared by the Department of Occupational Safety & Environmental Health (OSEH), under authority of the 42 CFR Part 73 rules pertaining to the roles and responsibility of the Responsible Official. This guideline supersedes OSEH guidelines “Select Agent Transfers” (dated June 1, 2003) and “USA PATRIOT Act Select Agent Security Requirements” (dated June 1, 2003).

SUMMARY: Researchers who wish to obtain or transfer Select Agent pathogens or regulated amounts of Select Agent toxins, specifically listed by CDC and USDA, must follow the procedures in this Guideline. Federal law requires the University to apply for and obtain a registration specific for each Laboratory Director (LD) who wishes to work with these highly-regulated materials, because they have the capacity to cause substantial harm to public health.

SCOPE: This Guideline applies to faculty and staff, students and visitors who wish to possess, use, receive, or transfer Select Agents as defined under current regulations.

REFERENCE REGULATION: The following laws and regulations are applicable to select agent use at the University of Michigan:

- CDC - Possession, Use, and Transfer of Select Agents and Toxins (42 CFR 73)
- USDA - Possession, Use, and Transfer of Biological Agents and Toxins (7 CFR 331)
- USA Patriot Act of 2001 (HR 3162, Public Act 107-56)

DEFINITIONS:

Access – an individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin. Only authorized persons are permitted access to select agents.

Authorized person – An individual who has been approved for access to Select Agents through the successful completion of the FBI security risk assessment and successfully completed the requirements set forth by the University of Michigan.

Personnel Suitability – Personnel with access to select agents or toxins should not display behaviors determined by the entity that would increase the risk of a theft, loss, or release of a select agent or toxin.

Recombinant nucleic acid – Molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell or molecules that result from their replication.

Synthetic nucleic acid – Molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules; or molecules that result from their replication.

Tier 1 Select Agents and Toxins - Designated select agents and toxins that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure; or public
confidence.

Institutional Biosafety Committee (IBC) – The research administrative oversight body chartered by the Regents of the University to function under the authority of the Vice President for Research. Formal charter calls for oversight with approval authority for all research involving recombinant DNA, infectious substances, biological toxins and select agent materials acquisition and use.

Responsible Official (RO) – The individual designated by the entity to act on its behalf when dealing with select agent materials or research efforts. This individual must have the authority and control to ensure compliance with the regulations.

Select agent – Biological agents and toxins determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. [CDC/USDA Select Agents List](#)

Excluded agents and toxins – These are attenuated strains of a select agent or an inactive form of a select toxin, which may be excluded from the requirements of the Select Agent Regulations. The list of excluded agents and toxins can be found at: [Select Agent and Toxins Exclusions](#).

Restricted person - A restricted individual is determined following the protocols established in OSEH guideline “Tier 1 Biological Select Agents and Toxins – Personnel Suitability” instituted March 26, 2013 and subsequent revisions.

**Restricted persons are prohibited from having access to select agents or toxins.**

RESPONSIBILITY: Everyone working at the University of Michigan has the right to expect a safe and healthy work environment. They also have a responsibility to help assure a safe and healthy environment for themselves and others. These responsibilities are detailed in the University of Michigan Academic [Laboratory and Research Safety Policy](#), issued jointly by the Department of Occupational Safety & Environmental Health (OSEH) and the Office of Research Ethics & Compliance (UMOR). Please click on the Policy link to view role specific responsibilities including but not limited to the following categories:

- All faculty, staff, other employees and students
- Graduate Student Research Assistants/Trainees
- Post-Doctoral Trainee/Fellow
- Laboratory Director (Faculty/Lab Manager/Supervisor
- Department Chair
- Facility Managers/Department Managers/Key Administrators/Chief Department Administrators
- Unit (School/College/Department) Safety Coordinators

Additional responsibilities specific to the implementation of this guideline follow.

**Deans, Directors and Department Heads**

- Assure that all Laboratory Directors are aware of procedures contained in this Guideline.
Laboratory Directors (LDs)
• Ensure projects involving select agents are in compliance with all regulatory requirements.
• Implement procedures in accordance with the institutional Select Agent Manual.
• Maintain an accurate inventory of select agents.
• Provide or arrange for required training for their research staff, including agent specific, biosecurity, biosafety, chemical safety and insider threat.
• Attend exercises and drills to test plans.

Authorized Personnel
• Access to select agents or toxins requires attendance at special trainings prior to handling select agents or toxins.
• Work with select agents or toxins must follow prescribed work practices.
• Select agents or toxins must be handled safely and must be secured properly when not in use.
• Provide notification to the Laboratory Director on the use of select agents or toxins to maintain a current inventory.
• Select agents or toxins must be disposed of properly when work is complete.

Responsible Official (RO)
• Ensure compliance with the select agent regulations.
• Receive and process requests for registration and transfer of select agents.
• Permit access to select agents for Authorized persons and revoke access as needed.
• Provide all necessary application and review documents to institutional and federal oversight agencies.
• Ensure that annual inspections are conducted for each laboratory where select agents or toxins are used or stored.
• Conduct inventory check at least annually.
• Maintain all required records associated with Select Agent use and destruction.
• Represent the institution during external audit by federal agencies.
• Maintain the UM registration (licensure) to possess Select Agents.
• Provide generic documents and technical support necessary for researchers to prepare safety procedures for the use of Select Agents.
• Witness and properly document the destruction of Select Agents.

University of Michigan Office of Research (UMOR)
• Provide the required oversight by academic administration through the Institutional Biosafety Committee (IBC) to review the applications for Select Agent registration prior to submittal to the federal authorities (CDC/USDA).
• The role of the IBC in this process is review and approval of the plan for biological containment and safety in the use of regulated select agents.

Division of Public Safety and Security (DPSS)
• Provide expertise for security measures in accordance with the institutional Biosecurity Plan.
• Provide the necessary security background checks for select agent applicants through Department of Justice.
• Monitor the suitability assessment program and review warranted suitability actions.
• Participate along with OSEH in internal audits of biosecurity.

PROCEDURES: The following procedures are established to ensure consistent application of the rules
and regulations for select agent use at the UM campus.

1.0 Select Agent or Toxin Use Approval Process

Approval to transfer or work with regulated select agents at UM is granted through a process that involves review by the appropriate academic decision-makers, the IBC, OSEH, the Division of Public Safety and Security (DPSS), and Information Technology Central Services. Each of these entities reviews an aspect of the Investigator’s plan to transfer or work with select agents. At the time of any request to transfer a regulated select agent or to commence work with such an agent on campus, including agents which are designated as “select” after the work has commenced, the RO will ensure application, registration and approval from the IBC and other designated institutional entities for such research.

The RO is the ultimate authority with jurisdiction on the UM campus to approve or disapprove the use of and access to select agents. In order to achieve approval, a number of steps are in place to assist in making the determination. Failure to complete the necessary steps and or maintain compliance once the program is approved will immediately result in stopping the access to the materials until such time mitigation of the issues is completed. The following items must be in place before the RO will register select agent materials with the CDC.

1.1 Personnel Security Risk Assessment (SRA)

Prior to working with or having access to select agents or toxins all individuals must undergo a security risk assessment (including fingerprinting) by the FBI. Refer to OSEH guideline “Tier 1 Biological Select Agents and Toxins – Personnel Suitability” for details on the process.

1.2 Suitability Assessment Program

A program must be in place to continually assess the personnel suitability of individuals working with Tier 1 select agents. The program is a combination of oversight by the RO and those responsible for the safe operation of the research and lab operations. Refer to OSEH guideline “Tier 1 Biological Select Agents and Toxins – Personnel Suitability” for details on the process.

1.3 Training

All authorized personnel are required to complete training once per year which includes an overview of Select Agents for All SRA-Approved Personnel as well as laboratory specific procedures and Select Agent security, including insider threat and emergency response procedures. The RO will maintain records of this training.

1.4 Security

The Laboratory Director must take precautions to ensure the security of the select agents or toxins by limiting access to storage and use locations. Samples must be secured in a locking refrigerator/freezer or a locking box within the refrigerator/freezer, to which physical access (key or combination)
is restricted. Select agent or toxin use locations must be secured by locking lab doors. Access must be restricted to only SRA authorized personnel.

1.5 Occupational Health Program

Workers who may be exposed to a Tier 1 BSAT will receive a medical evaluation prior to initiation of work or contact with these agents. The healthcare provider will review any previous and ongoing medical problems, current medications, allergies, and prior immunizations in order to determine an individual’s medical fitness to perform the duties of a specific position and what medical services are needed to permit the individual to safely assume the duties of the position.

2.0 Exemptions

LDs in possession of any select agents (including toxins) must contact the RO. The RO will coordinate the federal registration with the Select Agent Program for those LDs requiring registration.

2.1 Exempt Biological Materials

Certain select agent materials that meet regulatory criteria are exempt from registration with the CDC/APHIS. A list of exemption can be found on the CDC website, Select Agent Exemptions. All LDs working with exempt materials must notify the RO of any use of exempt select agents or toxins.

2.2 Exempt Toxins

Laboratories using quantities of toxins below federally established thresholds are required to follow the procedures listed below. Under the Regulations, certain listed toxins are exempt from the Select Agent registration provided that the Laboratory Director does not at any time possess more than the following aggregate amount of toxin. LDs in possession of any of the toxins listed below, must complete the OSEH Toxin Declaration Form

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

2.2.1 An inventory must be maintained for each select agent toxin. The Environmental Health and Safety Assistant (EHSA) is a web based chemical inventory system that must be used to maintain this inventory. The inventory must reflect the date and quantity of each purchase acquisition or transfer of toxin. The inventory must also reflect any toxin usage or destruction.
2.2.2 The RO will conduct periodic audits to verify the maintenance of the toxin inventory logs and to verify appropriate storage and use of the toxin.

2.2.3 The Laboratory Director must take precautions to ensure the security of the toxins by limiting access to the toxin storage and use locations. Toxin samples must be secured in a locking refrigerator/freezer or a locking box within the refrigerator/freezer, to which physical access (key or combination) is restricted. Toxin use locations should be secured by locking lab doors. Access should be limited to lab personnel that the Laboratory Director has authorized.

2.2.4 LDs must notify the RO if they will no longer be in possession of select agent toxins.

2.2.5 If a Laboratory Director seeks to possess more toxin than the exempt quantity, prior approval from the RO and the Federal Select Agent Program, must be obtained before acquiring the material.

3.0 Select Agent Records

- The RO must keep an up-to-date accurate list of all individuals approved for Select Agent access.
- The RO must maintain records pertaining to inventory, inspections; safety, security and emergency response plans; training; transfer documents and incidents reports.
- Laboratory Directors must maintain a current and accurate Select Agent inventory as described in the relevant regulation.
- An electronic card reader will record the time of entry for all approved users. The visitor’s name and his/her escort as well as the date, expected time, and purpose of visit are detailed on the written Visitor Entry Log.
- All records and logs must be kept for a minimum of 3 years.

4.0 Select Agent Transfers

All transfer of Select Agent materials outside of their approved and authorized containment area must be coordinated with the RO prior to it happening. Extramural transfers of Select Agents may not occur without prior authorization of the ROs at the entities of the transferor and recipient. Intramural transfer of the Select Agents must be approved by the RO before the transfer occurs, and may require additional approval of the IBC if the material is going to a different containment laboratory.

RELATED DOCUMENTS:
- CDC/NIH Guideline - Biosafety in Microbiological and Biomedical Laboratories, 5th ed.
- OSEH guideline “Tier 1 Biological Select Agents and Toxins – Personnel Suitability” instituted March 26, 2013 and subsequent revisions

TECHNICAL SUPPORT:
- All referenced guidelines, regulations, and other documents are available at OSEH (647-1143).