

## Acute Biological Toxins

This standard operating procedure (SOP) applies to working with acute biological toxins in UMass Amherst facilities. Many biological toxins are highly potent, and internalization of even relatively low doses may result in death or severe incapacitation. Laboratory workers can be exposed to biological toxins through a variety of routes, including inhalation of powders, aerosols, or volatile substances; ingestion; injection; and absorption through dermal, mucosal, or ocular tissues. Consequently, it is critically important for those working with biological toxins to understand and implement appropriate laboratory safety principles. Information on the safe use of biological toxins can be found in the most recent edition of [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#).

Research involving [exempt quantities of select toxins](#) and toxins that are exempt from federal regulations but have a mammalian LD<sub>50</sub> < 100 ug/kg bodyweight, such as those found [here](#), requires a written SOP for toxin-involved research processes, a formal risk assessment, and approval from the Institutional Biosafety Committee.

Please use the Risk Assessment Questionnaire (<https://forms.gle/yUMUQBQRvKZVNeyp6>) to provide information on your planned research. The Biosafety Office will work with you to conduct a formal risk assessment to determine the necessary containment level, facilities, procedures, practices, and expertise/training needed for the safe conduct of the project.

### *Minimum requirements when working with acute biological toxins*

<b>General Toxin Information</b>	Toxin name LD <sub>50</sub> in µg/kg body weight Routes of exposure (e.g. accidental inoculation, absorption, ingestion, inhalation) Target organ(s) Signs/symptoms of exposure Permissible amount (if a select toxin)
<b>Administrative Controls</b>	All personnel shall be familiar with the safety data sheet (SDS) for the toxin and a copy of the SDS shall be attached to the risk assessment.  It is the responsibility of the Principal Investigator (PI) to train all personnel regarding symptoms of toxin exposure, post-exposure management, spill cleanup and decontamination, proper use of engineering and work practice controls, personal protective equipment, and security requirements.  Exclude non-essential personnel from the work area when toxins are used and post the “No Entry, Toxin in Use” sign to warn/exclude personnel not directly involved in the work.

<p><b>Due Diligence</b></p>	<p>Even in excluded amounts, select toxins are subject to federal regulations for “Due Diligence” when transferring any amount of toxin to another investigator or individual due to concerns that someone might stockpile select toxins.</p> <p>The transferor must ensure and document that the recipient:</p> <ul style="list-style-type: none"> <li>• Is eligible to receive the select toxin</li> <li>• Has a legitimate need</li> </ul> <p><b>Transfer of select toxins to another UMass PI or to an individual outside of UMass shall be approved in advance by the Biosafety Office.</b></p> <p>Prior to transfer of select toxins the <i>Exempt Quantity Transfer Form</i> shall be completed and sent to EH&amp;S Biosafety for review (call 413-545-2682 for contact information).  <a href="https://ehs.umass.edu/exempt-quantity-select-toxin-transfer-form">https://ehs.umass.edu/exempt-quantity-select-toxin-transfer-form</a></p>
<p><b>Personal Protective Equipment (PPE)</b></p>	<p>The following PPE is required to be worn when working with toxins:</p> <ul style="list-style-type: none"> <li>• Long pants and full coverage shoes</li> <li>• Laboratory coat or gown</li> <li>• Latex or nitrile gloves</li> <li>• Safety glasses with side shields or goggles</li> </ul> <p>Contact the <a href="#">Respiratory Protection Program</a> to determine if respirators are required for working with this toxin.</p> <p><b><i>The Biosafety Office may require additional PPE based on the nature of the work described.</i></b></p>
<p><b>Security &amp; Storage</b></p>	<p><b>Select toxins</b> shall be stored in locked containers (e.g. freezer, refrigerator, cabinet, or drawer) or in a lock box affixed to a container such that the lock box cannot be removed.</p>
<p><b>Inventory</b></p>	<p><b>Select toxins:</b> It is important to ensure that the total amount of select toxin per PI is always maintained below their limits to remain exempt from registration with the CDC and the attendant restrictive requirements. Due to the severe penalties associated with non-compliance with the Select Agent Regulations, it is important that each laboratory using and storing select toxins maintains current inventory information for these substances.</p> <p>Failure to register a Select Toxin is now a criminal offense and can be punishable by up to five years in prison and/or \$500,000 in fines (Public Health Security &amp; Preparedness Response Act of 2002).</p>
<p><b>Engineering Controls</b></p>	<p>Engineering controls will be determined based on the hazards of the toxin and the nature of the research described.</p>

<p><b>Safe Work Practices</b></p>	<p>Purchase liquid toxin stocks whenever possible since working with powdered or dried toxins increases the risk of inhalational exposure and poses a tendency for electrostatic attachment to gloves, weighing spatulas, etc.</p> <p>Keep only minimum amounts of toxin on hand.</p> <p>Use the “Buddy System” when working with concentrations/amounts of toxin near or exceeding the LD50 dose for a human or when conducting higher risk procedures. Higher risk procedures include:</p> <ul style="list-style-type: none"> <li>• use of aerosol or splatter generating procedures</li> <li>• use of concentrated stocks or large quantities of toxins</li> <li>• work with powdered or dried toxins</li> <li>• use of needles or sharps</li> <li>• reconstitution of lyophilized toxin</li> </ul> <p>Minimize the use of sharps; if sharps are required, safety sharps shall be used wherever possible.</p> <p>Use plastic ware instead of glassware and use disposable materials whenever possible.</p> <p>If toxin/toxin solutions must be transported, place the primary container inside a leak-proof, non-breakable secondary container lined with absorbent material and labeled with a biohazard sticker.</p> <p>Upon completion of work, wipe all work surfaces and equipment with an approved cleansing agent following manufacturer’s instructions.</p> <p><b>Always wash hands after removing PPE and before leaving the work area.</b></p>
<p><b>Toxin Inactivation, and Waste Handling</b></p>	<p><u><b>Solid waste</b></u> Collection, inactivation, and disposal of all solid waste contaminated with or potentially contaminated with the toxin will be determined based on the hazards of the toxin. Sharps shall be collected in a red sharps container.</p> <p><u><b>Liquid waste</b></u> Collection, inactivation, and disposal of all liquid waste contaminated with or potentially contaminated with the toxin will be determined based on the hazards of the toxin.</p> <p>Prior to destruction of select toxins the <i>Select Toxin Destruction Form</i> shall be completed and sent to EH&amp;S Biosafety for review and assistance (call 413-545-2682 for contact information). <a href="https://ehs.umass.edu/toxin-destruction-form">https://ehs.umass.edu/toxin-destruction-form</a></p>

<p><b>Spill Handling</b></p>	<p>A biological spill kit will be available in the location where toxins are being used.</p> <p>Don PPE as specified in the risk assessment.</p> <p>Cover spill with paper towels or other absorbent material.</p> <p>Apply approved cleansing agent to the spill, starting at the perimeter and moving towards the center. Follow manufacturer’s instructions for effective use of cleaning agent.</p>
<p><b>Exposure Management</b></p>	<p><b><u>Skin or Wound Exposures</u></b>  Move to (or move person to) uncontaminated area and remove contaminated PPE/clothing and place in red biohazard bag.</p> <p>Wash skin and wound exposures with soap and water for a minimum of 15 minutes.</p> <p>For spills of large quantities of toxin onto clothing or skin, immediately use the emergency shower or soap and water for a minimum of 15 minutes.</p> <p><b><u>Eye or Mucous Membrane Exposure</u></b>  Use emergency eye wash for a minimum of 15 minutes.</p> <p><b><u>For All Exposures</u></b>  Review SDS for symptoms of exposure/delayed onset effects.</p> <p>Obtain medical attention:</p> <ul style="list-style-type: none"> <li>• Call 911 for life-threatening emergencies.</li> <li>• If non-life threatening, seek post exposure evaluation/treatment (University Health Services or an emergency room) within two hours of exposure.</li> </ul> <p>Submit a Notice of Injury form if the exposed individual is an employee of UMass.</p> <p>Report incident to PI and submit a Laboratory Incident Report form to the EH&amp;S Biosafety Office (413-545-2682).</p>

A formal risk assessment document shall be signed and dated by the PI and all project personnel, indicating that they understand the hazards, risks, and mitigation measures for working with the toxin and agree to adhere to all requirements. The Risk Assessment shall be reviewed annually and updated as needed. All personnel shall sign and date any time the Risk Assessment is updated.