

## MSU Biological Toxin Policy

Biological toxins are toxic substances that can be produced by microorganisms, animals, or plants. Biological toxins are nonreplicating, noninfectious biological materials that can be hazardous even in small quantities.

This policy does not cover the storage or handling of toxic chemicals. See [MSU Chemical Safety](#) website for questions regarding chemicals.

This document describes Montana State University's (MSU) policies and relevant Federal regulations that may apply to research with biological toxins. This policy includes Institutional Biosafety Committee (IBC), Federal Select Agent, and Export Compliance regulations.

### Biological Toxins Requiring IBC Approval

Research at MSU involving biological toxins, including select agent toxins, must be approved by the IBC prior to initiation of work.

The use of lipopolysaccharide (LPS) and its derivatives are exempt from the requirement of IBC approval prior to initiation of work.

Work involving recombinant or synthetic nucleic acid molecules that encode the active subunit(s) of a biological toxin must also have IBC approval before initiation work. In some cases, additional review by the National Institutes of Health Office of Biotechnology Activities (NIH-OBA) as indicated in the NIH guidelines may be required.

### Handling of Lyophilized or Powdered Toxins

Lyophilized and powdered toxins must be handled inside of a biosafety cabinet (BSC) or chemical fume hood until they are reconstituted/dissolved into liquid.

### Select Agent Toxins

Certain biological toxins are classified by the Federal Government as Select Toxins due to their potential threat to public safety and health. The possession, use, or transfer of these biological toxins is highly regulated by the Federal Select Agent Program. Investigators using Select Agent Toxins are not required to register with the Select Agent Program if the amount does not exceed the permissible toxin amounts (see Appendix 1).

Investigators that possess a Select Toxin less than or equal to the permissible amount must maintain an inventory of the amount of the Select Toxin present in the laboratory. This inventory should document the number of vials, amount in each, amount remaining (if applicable) after each use, and how the toxin was inactivated when no longer needed for experiments. To meet this requirement, investigators should use the MSU Record of Excluded Select Toxin Use and Disposal form (Appendix 2).

The Federal Select Agent Program states that Investigators must show due diligence regarding any transfer of a Select Toxin in order to prevent attempts by nefarious parties to stockpile toxins classified as a Select Toxin. In accordance with 42 CFR 73.16, Investigators must document the recipient(s) of any Select Toxin and provide evidence that the individual(s) has a legitimate purpose to possess toxins. Prior to any transfer of a Select Toxin,



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Compliance

Investigators must submit an Application for Request of an Excluded Select Toxin form (Appendix 3). This form must be approved by the IBC prior to shipping the toxin to the recipient.

### [Export Controlled Toxins](#)

Certain biological toxins, including genetic elements encoding these toxins, along with technical information which may enable the development or production of such toxins and genetic elements, are restricted for export by the U.S. Department of Commerce and/or the U.S. Department of State. These materials and related technical information may require an export license before sharing materials or disclosure of technical information to non-U.S. persons, regardless of whether such sharing or disclosure takes place within the U.S. or abroad. . To see if the toxin requires IBC approval, please consult the table in Appendix 1, or contact the Biosafety Officer.