MONTANA STATE UNIVERSITY
Research Integrity & Compliance

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IBC Approval Date: 2-12-2025

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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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.

Table of Biological Toxins

The table indicates the LD50 for some acute biological toxins, the permissible amounts of Select Toxins, and the toxins that are subject to Export Control regulations.

Toxin	LD_{50} (µg/kg)	Select Agent	Export Compliance
Abrin	0.7	Y (1000 mg)	Y
Aerolysin	7		
Aflatoxins			Y
B-bungarotoxin	14		
Botulinum toxins	0.0004 to 0.0025	Y (1 mg)	Y
Caeruleotoxin	53		
Cereolysin	40 to 80		
Cholera toxin	250		Y
Clostridium difficile	0.5 to 220		
Clostridium perfringens	0.1 to 1500		Y
Conotoxins	12 to 30	a-conotoxins only, (200 mg)	Y
Crotoxin	12 to 30		
Diacetoxyscripenol toxin		Y (10,000 mg)	Y
Diphtheria toxin	0.1		
HT-2 toxin	5 to 10		Y
Listeria listeriolysin or hemolysin	3 to 10		
Leukocidin	50		
Microsystin (Cyanoginosin)			Y
Modeccin toxin	1 to 10		Y
Nematocyst toxins	33 to 70		
Notexin	25		
Pertussis toxin	15		
Pneumolysin	1.5		
Pseudomonas aeruginosa exotoxin A	3		
Ricin	2.7	Y (1000 mg)	Y
Saxitoxin	8	Y (500 mg)	Y
Shiga Toxin	20		Y
Shigella dysenteriae neurotoxin	1.3		
Staphylococcal aureus toxins	2 to 25	Subtypes A-E (100 mg)	Y
Streptolysin S	25		
Taipoxin	2		
Tetanus toxin	0.001		
T-2 toxin	5 to 10	Y (10,000 mg)	Y
Tetrodotoxin	8	Y (500 mg)	Y
Verotoxin			Y
Viscum Album lectin 1 (Vixumin)	2.4 to 80		Y
Volkensin toxin	1.4		Y
Yersinia pestis murine toxin	10		

Record of Excluded Select Toxin Use and Disposal

- Please use one form for each toxin purchase or acquisition.
- Keep this record for a minimum of three years after all of the toxin on this form has been destroyed.

Select Toxins are not required to register with the Federal Government if the amount under the control of a Principal Investigator does not exceed at any time the permissible toxin amounts, which are indicated below. Principle Investigators that possess a Select Toxin equal to or under the permissible amount must maintain an inventory of the amount of the Select Toxin present in the laboratory at any given time. This inventory should document the number of vials containing toxin, amount in each, amount remaining (if applicable) after each use, and how the toxin was inactivated when no longer needed for experiments. You must also have a current IBC approval number and the appropriate training to possess any of the following Select Toxins in any quantity:

PERMISSIBLE TOXIN AMOUNTS

HHS Toxins [§73.3(d)(7)]	Amount
Abrin	1000 mg
Botulinum neurotoxins	1 mg
Short, paralytic alpha conotoxins	200 mg
Diacetoxyscirpenol (DAS)	10,000 mg
Ricin	1000 mg
Saxitoxin	500 mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D, and E)	100 mg
T-2 toxin	10,000 mg
Tetrodotoxin	500 mg

Building	
Room #	
Room Phone Number	
Principal Investigator	
Principal Investigator Phone Number	
Lab Supervisor	
Lab Supervisor Phone Number	
IBC Protocol #	
IBC Approval Date	

Toxin Name:	
Total Amount Received:	
Concentration:	
Maximum Permissible Toxin Amount:	
LD50:	
Manufacturer/Source:	
Catalog #:	
Ordered By (Name and Date):	
Received By :	

Vial ID	Date and Time created	Location (Freezer/Self/Rack /Box)	Volume	Removed by Whom and When	Purpose of Use	Destruction Method

APPLICATION FOR REQUEST OF AN EXCLUDED SELECT TOXIN

Montana State University Transfer of Excluded Select Toxins is in accordance with 42 CFR §73.

1) Recipient (Name, organization, complete, address, telephone, email address and fax number of individual who will receive and be responsible for the toxin)	2) Transferor: (Name and Address)

3) Describe the toxin to be shipped (Toxin name, amount to be transferred, and date of expected transfer)

4) What is the proposed use of this toxin? (Also, describe facilities/biosafety procedures and attach any relevant Biosafety protocols that have been approved by your Institutional Biosafety Committee)

5) Do you already have the requested toxin in your possession?
6) Have you ever received/requested this toxin in the past? If yes, how often do you receive this toxin?
7) Will you be using the toxin for its intended propose as you describe in question 4 or are you planning to give the toxin to someone else?
I certify that this toxin will be used in accordance with 42 CFR 73 and I have a legitimate need (i.e., reasonably justified by a prophylactic, protective, bon fide research, or other peaceful purpose) to handle or use such toxin.

8) Signature of Recipient	9) Typed Name and Title
10) Date	IBC Approval Date: