**BIOLOGICAL TOXIN REGISTRATION FORM**

**IBC Use Only**

Registration # Review Date:

For Registration of Naturally Occurring Biological Toxins or their Synthetic Analogues

**THIS APPLICATION MUST BE TYPEWRITTEN**

**Section I. Personnel**

1. Principal Investigator: M.D. [ ] Ph.D. [ ] Other:

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| **Section II. Type and Location of Toxin Research** |
| 1. Project Title: |
| 2. Grant # (if applicable): |
| 3. AGENT DESCRIPTION (Check all that apply):[ ] Abrin [ ] Conotoxins [ ] Diacetoxyscirpenol (DAS)[ ] Ricin [ ] Saxitoxin [ ] Shiga-like Ribosome Inactivating Proteins [ ] Tetrodotoxin [ ] Botulinum Neurotoxins [ ] Clostridium Perfringens Toxins[ ] Shigatoxin [ ] Staphylococcal Enterotoxins [ ] T-2 Toxin [ ] Other (List Specific Toxin(s)): |
| 1. For toxins listed in 3 above, will total amounts on hand at any one time (stored and in use) exceed the following limits:
	* 0.5 mg Botulinum neurotoxins
	* 5.0 mg *Staphylococcal* enterotoxins
	* 100 mg Abrin, *Clostridium perfringens* epsilon toxin, conotoxin, ricin, saxitoxin, shigatoxin, shiga-like ribosome inactivating protein, or tetrodotoxin
	* 1,000 mg diacetoxyscirpenol (DAS) or T-2 toxin
 | [ ] Yes [ ] NoTotal amount: mg |
| 1. Indicate the building and room number where toxins listed in 3 above are stored:
 | Building: Room(s): |
| 1. Will the toxin be in powdered form at any point?
 | [ ] Yes [ ] No |
| 7. Indicate the building and room number where toxins listed in 3 above are handled: | Building: Room(s): |
| 8. Will research involve human subjects? | [ ] Yes [ ] No |
| 9. Will research involve nucleic acids that code for functional forms of toxins listed in 3 above? | [ ] Yes [ ] No |
| 10. Will research involve whole animals? | [ ] Yes [ ] No |
| 11. Do you request medical surveillance? | [ ] Yes [ ] No |

Yes [ ] No [ ]

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| **Section III. Equipment, Facilities, & Security** |
| 1. Mark all pieces of equipment that apply to this project that have the potential to aerosolize toxin when used: |
| Centrifuge | Yes [ ] No [ ] Homogenizer |  | Yes [ ] No [ ] |
| Blender | Yes [ ] No [ ] Vortex Mixer |  | Yes [ ] No [ ] |
| Sonicator | Yes [ ] No [ ] Other: |  |  |
| 2. Laboratory is equipped with at least one class II biological safety cabinet or a fume hood in which aerosol-producing tasks can be conducted? |  |
| 3. Toxins are secured in a locked refrigerator, freezer, or storage cabinet when not in use? |  |
| 4. An accurate inventory is maintained and physical inventory of toxin stocks is conducted on a regular basis? |  |
| 5. Access to laboratories where toxins are handled or stored is restricted to those individuals with approved security risk assessments?\* |  |

Yes [ ] No [ ]

Yes [ ] No [ ]

Yes [ ] No [ ]

* *Applies only to those laboratories that exceed the limits identified in Section II above.*

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| **Section IV. Research Summary** |
| Provide a **short, clear summary** of your research that involves the toxins listed in Section II above. Your proposed experiments should be described in lay terms that will explain their essential features. Avoid jargon and excess technical detail. Briefly explain and justify the use of toxins listed in Section II. |

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| **Section V. Risk Assessment**Address each of the following items and include any other data that you feel has important bearing upon the safety of this project: |
| 1. Identify and describe the major health risk(s) to humans, animals, and the environment associated with the toxins identified in Section II.
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| 2. Are vaccinations available to protect against the toxin and is there a known antidote(s) for the proposed toxin if exposed? |
| 3. Describe all procedures and tasks related to this research where laboratory personnel may be exposed to toxins identified in Section II. Examples include procedures where accidental exposure may occur by direct contamination of mouth, eyes or other mucous membranes; by inadvertent aerosol generation; and by needle-sticks or other accidents that may compromise the normal barrier of the skin. Specifically address whether toxins will be diluted in solvents that can absorb through the skin (e.g. dimethyl sulfoxide, etc.). |
| 4. List the amount and/or concentration of toxin that will be used during the tasks and procedures outlined above. Is the amount/concentration enough to pose a significant hazard to laboratory personnel in the event of an exposure incident? Why or why not? |
| 5. Based on the tasks and procedures outlined above, and based on the amounts and concentrations of toxin being handled, identify and describe the specific safety measures that will be used to protect laboratory personnel. |
| 6. Describe the methods that will be used to decontaminate equipment and work surfaces, and to inactivate toxin following a spill. Specify the disinfectant chemical, concentration and contact time. |

Please also provide a copy of your lab Standard Operating Procedures (SOP) for work with Toxins, or a laboratory Chemical Hygiene Plan (CHP), edited to include details of the procedures for working with the toxin being registered.

Alternatively, the IBC has developed an SOP template for working with biological toxins (following pages). Please edit if you plan to adopt this template (if not please delete the template from this form). **Please note that this template includes all the elements required by the IBC that should be addressed in your lab SOP or CHP**.

Provide documentation of training. A template is available at the end of this document.

**Once you have completed the registration form, please attach a copy, plus your lab SOPs/CHP and training documentation as a "Document" to your BioRAFT Registration.**

**BIOLOGICAL TOXIN TEMPLATE SOP**

Adapted from the University of Washington Template

 *[Customize text in parentheses and brackets to specific procedures and equipment in your laboratory. Please refer to the Biosafety in Microbiological and Biomedical Laboratories, Appendix I: Guidelines for work with Toxin of Biological Origin for more information, https://www.cdc.gov/biosafety/publications/bmbl5/bmbl5\_appendixi.pdf#x2013.]*

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| Standard Operating Procedures for *[Toxin]* |
| #1 Chemicals/Hazards | [*Obtain specific toxin hazard information from MSDS/SDS*.*]* CAS number: *[XXX]*Routes of exposure: *[XXX]*How exposure might occur: *[XXX]*Target organs: *[XXX]*Signs/symptoms of exposure: *[XXX]* |
| #2 Prior to Work | Hazardous chemical and specific SOP training will be provided to personnel working with toxin and any other personnel authorized or required to be in the laboratory during toxin work.Appropriate inactivation method(s) for [*toxin*] will be determined and supplies for inactivation and spill cleanup of *[toxin]* will be readily available.*[List vaccinations or antitoxins required or recommended for toxin]*. If vaccinations or antitoxins are required, contact Occupational and Environmental Health and Safety at 801-581-6590. |
| #3 Environmental/Ventilation Controls | Work with *[toxin]* will be performed in a *[chemical fume hood/Biological Safety cabinet (BSC)]*.  *List the type of BSC to be used (e.g. Class II, Type A2).*In-line HEPA filters will be used on vacuum lines.Safety centrifuge cups or sealed rotors will be used if centrifuging materials containing *[toxin]*, and the outside surfaces will be routinely decontaminated after each use. |
| #4 Personal Protective Equipment (PPE) | The following PPE will be worn when working with *[toxin]*: *[Customize list]** Laboratory coat or gown with long cuffed sleeves
* Disposable lab coat
* Disposable sleeves
* Safety glasses with side shields or chemical safety goggles
* Face protection such as a face shield if splash/spatter possible
* Gloves *[type]* that are impervious to *[toxin]* and diluent
* Respiratory protection *[if aerosol hazard is present] If respirators are used the worker must be enrolled in the Respiratory protection program; contact OEHS for information (*[*http://d2vxd53ymoe6ju.cloudfront.net/wp-content/uploads/sites/4/20160922155338/Resp-Prot-Program-rev.2016.pdf*](http://d2vxd53ymoe6ju.cloudfront.net/wp-content/uploads/sites/4/20160922155338/Resp-Prot-Program-rev.2016.pdf)*).*

Gloves must be changed immediately if contaminated, torn, or punctured. |
| #5 Special Handling Procedures & Storage Requirements | **HANDLING**Prep* Sign will be posted on the room door when toxin is in use stating: “Toxins in Use -- Authorized Personnel Only.”
* All preparation of *[toxin]* will be performed over plastic-backed absorbent pads in a *[fume hood/BSC]*. Pads will be disposed of immediately upon contamination and after completion of tasks.
* Describe how toxin will be prepared*: [Example: Vials of [toxin] will be purchased in pre-weighed powder form and then reconstituted in a [fume hood/biological safety cabinet (BSC)]. Weighing the [toxin] is not necessary as reconstitution will occur in the purchased vial and then aliquoted into vials with caps.]*

Use* Only needle locking (Luer-Lock type) syringes or disposable syringe units will be used for injection or aspiration of *[toxin]*.
* A sharps container will be in the immediate vicinity for safe sharps disposal.
* Containers will be decontaminated before they are removed from *[fume hood/BSC]*.
* The *[fume hood/BSC]* will be decontaminated upon completion of tasks with *[decontaminant and concentration]* for *[contact time]*.
* All potentially contaminated disposable items will be placed in a hazardous waste bag and decontaminated before disposal.
* Hands will be washed upon completion of tasks.

**STORAGE*** *[Toxin]* will be stored in locked *[freezer/refrigerator/cabinet/box/other]* in *[secure location room #]*.

**TRANSPORT*** *[Toxin]* will be transported in labeled and sealed non-breakable secondary containers.
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| #6 Spill and Accident Procedures*[Specific cleaning, decontamination agents (and contact times)/equipment and waste disposal procedures must be determined.]* | All spills will be cleaned by properly protected and trained personnel only. Wash hands thoroughly after completing any spill clean-up. If you are not trained or comfortable cleaning up a spill, call OEHS for assistance at 801-581-6590. If it is an emergency (risk of exposure to others such as an on-going toxin release), call 911.**Liquid spills:**Personnel cleaning up a liquid spill will wear a lab coat/gown with cuffed sleeves (or disposable sleeves), goggles, and two pairs of nitrile gloves. Cover spill with absorbent paper towels and apply *[inactivating agent + concentration]*, starting at the perimeter and working towards the center, allowing *[XX min]* contact time to deactivate *[toxin]*. Clean the spill area with *[inactivating agent]*, then soap and water. The decontaminated spill waste will be double bagged and disposed of in the biohazard waste container. **Powder spills inside of [*fume hood/BSC]*:**Personnel cleaning up a powder spill will wear a lab coat/gown with cuffed sleeves (or disposable sleeves), goggles, and two pairs of nitrile gloves. Gently cover powder spill with dampened absorbent paper towels to avoid raising dust. Apply *[inactivating agent + concentration]*, starting at the perimeter and working towards the center, allowing *[XX min]* contact time to deactivate *[toxin]*. Clean the spill area with *[inactivating agent]*, then soap and water. The decontaminated spill waste will be double bagged and disposed of in the biohazard waste container. **Powder spills outside of a *[fume hood/BSC]*:**Remove all personnel from the room and restrict access; do not attempt to clean up the spill unless personnel are authorized to use a respirator. If personnel are not cleared to use a respirator, report the spill by notifying OEHS (at 801-581-6590). Tell them that a spill has occurred, and you need OEHS to assist with the spill cleanup. Be prepared to provide the following information: * Name and phone number of knowledgeable person that can be contacted: *[emergency contact name and phone number]*
* *[Toxin name]*, concentration and amount spilled, liquid or solid spill
* Number of injured, if any
* Location of spill

This information can also be used in reporting to the Emergency Department after potential exposure.Personnel cleaning up a powder spill will wear a lab coat/gown with cuffed sleeves [*or disposable sleeves*], goggles, two pairs of nitrile gloves and a respirator. Gently cover powder spill with dampened absorbent paper towels to avoid raising dust. Apply *[inactivating agent + concentration]*, starting at the perimeter and working towards the center, allowing *[XX min]* contact time to deactivate *[toxin]*. Clean the spill area with *[inactivating agent]*, then soap and water. The decontaminated spill waste will be double bagged and disposed of in the biohazard waste container.For questions on spill cleanup, contact OEHS at 801-581-6590 for guidance.Wash hands thoroughly after completing any spill clean-up. |
| **EXPOSURE PROCEDURES****In Case of Emergency** | 1. **Provide First Aid Immediately**
* For sharps injury (needlestick or subcutaneous exposure), scrub exposed area thoroughly for 15 minutes using warm water and soap.
* For skin exposure, wash the area with soap and water. For large exposures, use the nearest safety shower for 15 minutes. Stay under the shower and remove clothing. Use a clean lab coat or spare clothing for cover-up.
* For eye exposure, use the eye wash for 15 minutes while holding eyelids open.
* For inhalation, move out of contaminated area. Get medical help.
1. **Get Help**
* Call 911 or go to nearest Emergency Department (ED). Give details of exposure, i.e. agent, dose, route of exposure, time since exposure. Bring to the ED the MSDS/SDS and this SOP.
* Notify your supervisor as soon as possible for assistance.
* Secure area before leaving.
1. **Report Incident to Occupational and Environmental Health & Safety**
* If serious accident, hospitalization or fatality, notify OEHS immediately after providing first aid and/or getting help.
	+ Call at 801-581-6590.
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| #7 Waste Disposal and Cleaning | Any waste *[toxin]* will be decontaminated or autoclaved as appropriate before disposal or given to OEHS for disposal whenever possible.Work space surfaces must be wiped down after completion of tasks with *[inactivating agent + concentration]* during the length of the experiment. Absorbent pads will be replaced after completion of tasks or immediately if contaminated. Used and potentially contaminated absorbent pads, PPE, etc. will be placed in a hazardous waste bag and autoclaved. If in-lab inactivation is not possible for *[toxin]* waste, it must be managed as hazardous chemical waste. Be aware that some form of treatment in the lab may be required before it can be managed as chemical waste. Contact OEHS at 801-581-6590 for disposal instructions. For chemical waste pick up complete a request through the lab management system (<http://oehs.utah.edu/topics/lab-management-system>).  |
| #8 Special Precautions for Use of *[Toxin]* in Animals*(This section must be completed if working with toxin in animals)**Identify where animals will be injected, housed and any special precautions/warnings for animal handlers.*  | Use of toxins in animals will be documented and approved by IACUC.*[Give detailed procedures for safely completing tasks, containment, decontamination information, and any special disposal requirements.]**[Animals will be anesthetized or placed into a restraining apparatus before procedures using [toxin] are performed. Once the animal has been properly fitted into the restraining apparatus, the syringe will be loaded just prior to injection.]*After procedures are complete, the restraining apparatus and surrounding work station will be decontaminated *[inactivating agent + concentration]*. All reusable lab equipment will be autoclaved.*[Give any special disposal requirements]* |
| #9 Approval Required | The protocol must be approved by the Institutional Biosafety Committee prior to commencement. All staff working with *[toxin]* must be trained on this SOP prior to starting work. They must also be trained on the *[toxin]* MSDS/SDS, and it must be readily available in the laboratory. All training must be documented and maintained by the PI. |
| #10 Decontamination | All surfaces will be decontaminated with *[inactivating agent + concentration]* after removing the plastic backed pads. All reusable lab equipment will be autoclaved. Note that some disinfecting agents may not deactivate *[toxin]*. |
| #11 Designated Area | All work with [*toxin*] must be done in a designated laboratory, work space and *[fume hood/BSC]*. Signage must be placed on door to room when *[toxin]* is used. This work will be conducted in *[Room #]* |
| Name: | Title: |
| Signature:  | Date: |

***\*\* Training content must include a description of the toxins and laboratory procedures that will be used, health effects, signs & symptoms of exposure, routes of exposure, precautions to prevent exposure, spill clean-up procedures, personal protective equipment use and cleaning, post- exposure response, decontamination, and waste disposal.***

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| ***[Laboratory Name]*****Documentation of Training****Standard Operating Procedure for *[Toxin]*** |
| **Name** | **SOP Training Date** | **Signature** |
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