**Appendix A - Research Involving the Use or Possession of Permissible Quantity Select Agent Toxins**

**IBC #**

### Section I Administrative Information

**Please complete this form and attach it to your IBC application in eSirius. Submissions separate from the formal application in eSirius will not be accepted.**

The [Select Agent Toxins list](http://www.selectagents.gov/SelectAgentsandToxins.html) includes some commonly used research materials. University policy is that all toxins on this list are required to be registered with the IBC. There are threshold limits that are allowed under the regulations without full registration. Refer to the [Federal Select Agent Program](http://www.selectagents.gov/SelectAgentsandToxins.html) for information about exclusions, restricted experiments, nucleic acids, permissible amounts, and nonfunctional Select Agent (SA) Toxins.

A letter of support, from your Department Chair and/or Division Head, must accompany this application. The letter of support may be a pdf on departmental letterhead, or may be sent to [ibc@ucdenver.edu](mailto:ibc@ucdenver.edu) in email format directly from the Department Chair and/or Division Head. A new letter of support must be submitted with each protocol renewal (every three years).

If your laboratory plans to sponsor a foreign national employee on a H-1B, H-1B1, L-1 or O-1 type visa, you must work with the Office of Regulatory Compliance/Export Control and the International Students and Scholar Services office to determine if a deemed export license is required. Information about this requirement can be found on the [Export Control website](http://www.ucdenver.edu/research/ORC/EC/Pages/ForeignEmp.aspx).

Individuals who will work with Select Agent products must receive all institutionally required training. Please contact Environmental Health & Safety for further information on required training and handling of Select Agent products prior to starting work.

**Section II Select Agent Toxin Information**

1. **Specific SA Toxins Requested to be Used -** Please review the [Permissible Toxin Amount](http://www.selectagents.gov/PermissibleToxinAmounts.html) to complete this section.  NA – go to B. below

Complete this section **for each Select Agent Toxin** **to be used** in your laboratory. Any possession, use, or transfer above the limits REQUIRES full Select Agents Program registration with the appropriate authorities. (*expand this table as necessary*)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of Toxin(s)** | **Max. amt. in possession in the lab at any time** | **Max. amt. to be ordered at any one time** | **Toxin was Obtained / Purchased From** | **List how Toxin(s) will be used:** | |
|  |  |  |  | *In vitro*  I*n vivo* | IACUC Protocol #  & Approval Date |
|  |  |  |  | *In vitro*  I*n vivo* | IACUC Protocol #  & Approval Date |

**B. Specific SA Toxins in POSSESSION ONLY and NOT BEING USED**

Complete this section **for each Select Agent Toxin** **in possession only and not being used** in your laboratory. Any possession above the limits REQUIRES full Select Agents Program registration with the appropriate authorities. (*expand this table as necessary*)

|  |  |  |
| --- | --- | --- |
| **Name of Toxin(s)** | **Max. amt. in possession in the lab at any time** | **Toxin was Obtained / Purchased From** |
|  |  |  |
|  |  |  |

[**Permissible Toxin Amount**](http://www.selectagents.gov/PermissibleToxinAmounts.html)

|  |  |
| --- | --- |
| **HHS Toxins [§73.3(d)(3)]** | **Amount** |
| Abrin | 1000 mg |
| Botulinum neurotoxins | 1 mg |
| Short, paralytic alpha conotoxins | 100 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 |

**NOTE** Disposal of all SA Toxin(s) must be in accordance with the federal regulations, through the UCD Hazardous Chemical Waste section. All personnel must be current on all UCD Hazardous Chemical Waste Generator Training before you will receive authorization by the IBC for this material.

**C. Research/Project Specific Information – complete this for all Toxins listed in Section II A.**

1. State the objectives of the work to be performed with the Select Agent Toxin(s). Include sufficient information on methods and lab procedures for appropriate IBC review**.** Specify if work will involve live organisms, animals, introduction of antibiotic resistance to live organisms, and/or recombinant DNA experiments.

2. Complete a *Standard Operating Procedure (SOP) for Research Involving Permissible Quantity Select Agent (SA) Toxin* for the Toxin(s) listed in Section II A. above. This SOP must demonstrate proficiency in laboratory procedures prior to beginning work with SA Toxins. On the job training must be documented and on file for each individual.

**Section III Compliance with Federal Regulations**

**A. Export Control and “Deemed Exports”**

Does your laboratory plans to sponsor a foreign national employee on a H-1B, H-1B1, L-1 or O-1 type visa?

Yes  No

**If YES**, you must work with the Office of Regulatory Compliance/Export Control and the International Students and Scholar Services office to determine if a deemed export license is required. Information about this requirement can be found on the [Export Control website](http://www.ucdenver.edu/research/ORC/EC/Pages/ForeignEmp.aspx).

**B. Principal Investigator Acknowledgement of Roles and Responsibilities**

By submitting this form to the IBC as part of a full IBC protocol application, the PI agrees to the following:

“I acknowledge that I must meet and adhere to all requirements and restrictions of the most current [Federal Select Agent Program](http://www.selectagents.gov/index.html), the University directives for H-1B and O-1 visas, and any other applicable University policies, for the proposed research, to be reviewed and approved by the Institutional Biosafety Committee and potentially subject to the review and approval and registration with the designated federal agencies, prior to obtaining these materials and initiating experiments with these materials.

I accept responsibility for the safe conduct of the experiments conducted at the assigned Biosafety Level or other containment.

I understand that it is my responsibility to assure that all personnel working in my laboratory with any SA Toxin are fully trained on the Standard Operating Procedures about their specific hazards, proper actions for safe use, steps to take in case of accidents, and are provided with all necessary safety equipment and instructions in its use.”

|  |
| --- |
| This space is for Biosafety Office Use  **SA Toxin Laboratory Audit Results**  IBC Expiration Date:  Auditor:       Audit Date:  Completed Inventory  Secured Storage  Usage Log Present  All Containers, Tubes, Vials, etc. Clearly Labeled  Lab Specific Training  Can Identify Handwashing Sink, Eyewash, Shower |