PURPOSE & Description

The purpose of this SOP is to delineate the minimum standards for the full length or use of A subunit containing cholera toxin when administered to rodents by injection. The A subunit of cholera toxin contains the enzymatically active domain which is responsible for the toxic effects virulent factor from Vibrio cholerae that leads to severe diarrhea followed by dehydration in humans and is considered an acute toxin when administered via injection.

Scope

This SOP applies to the Principal Investigator (PI) and their laboratory staff.

This SOP applies only to use of any form of cholera toxin containing A Subunit.

This SOP does not apply to cholera toxin administered orally.

Responsibilities

PIs are responsible for training of their laboratory staff and continued participation in following safety guidelines.

PI and laboratory staff are responsible for following the [Policy on Handling Animals Exposed to Biological Hazards](https://iacuc.ufl.edu/secure/wp-content/uploads/sites/3/Policy-on-Handling-Animals-Exposed-to-Biological-Hazards.pdf).

Definitions

* **Clear time** – The period of time required to allow for excretion of a hazardous chemical before standard handling practices can be used.
* **Safety-engineered sharps** –a non-needle sharp or needle device with a built-in safety feature or mechanisms that effectively reduces the risk of an exposure incident. More information on safety engineered sharps can be found here: [[UF EHS Safety-Engineered Sharps Fact Sheet](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D)](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D).

Hazard Identification & Control Measures

**Potential Hazards**

* **Physical Hazards**
	+ Needlestick
* **Chemical Hazards**
	+ Inhalation; powdered form
	+ Acute toxicity, Oral
	+ Acute toxicity, Dermal

**Engineering Controls / Administrative Controls**

* Dry forms of cholera toxin must be used in a Chemical Fume Hood, or Biosafety Cabinet (Class II).
* Use of a Biosafety Cabinet (BSC) or Chemical Fume Hood (CFH) is required for agent administration and cage manipulation.
* Syringes used for injection should comply with the details outlined in [UF EHS Safety-Engineered Sharps Fact Sheet](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D).
* Rodents should be appropriately restrained prior to administration, as described in the approved Animal Use Protocol (AUP).
* Gloves should be changed frequently, at a minimum when contaminated with cholera toxin or torn, and before handling animals in other experimental groups.
* Hands and arms should be washed with soap and water upon completion of procedure.

**Personal Protective Equipment (PPE)**

* Appropriate lab attire including skin protection, closed shoes, and eye protection.
* Long-sleeve gown or long-sleeve dedicated lab coat
* Double Gloves for agent administration
	+ Single gloves for cage change

Procedure

* Prior to working with biological hazards in rodents, all work must be described in an approved AUP.
* Contact the ACS facility manager where the rodents are housed at least 48 hours prior to use of the biological hazard **IF** ABSL1i housing following the [Policy on Handling Animals Exposed to Biological Hazards](https://iacuc.ufl.edu/secure/wp-content/uploads/sites/3/Policy-on-Handling-Animals-Exposed-to-Biological-Hazards.pdf).

Special Handling and Storage Requirements

* Cholera toxin administered via injection has no clear time. Cholera toxin introduced via injection should not be present in the urine, however, bedding must be collected and autoclaved prior to disposal for the first cage change post administration to account for any potential leakage from injection site.
* Primary methods of transport are syringes placed in a conical tube and secured using parafilm or a safety syringe/needle combination, with protective sheath that has a transport position.
* Secondary transport containers or storage must be shatter-resistant, rigid, shock-resistant, leak-proof, and made of a non-reactive material which can be easily cleaned and decontaminated in the event of a leak.
* Personal protective equipment as described above must be worn when handling cholera toxin, in addition to any PPE requirements of the animal room. Hands and arms should be washed with soap and water after removing PPE.
* Needles and sharps used with cholera toxin must be disposed of immediately in a sharps container. Do not reuse, bend, or recap needles. Safety-engineered sharps should be used whenever possible.
* An approved solution must be used for decontamination of equipment and areas exposed to cholera toxin (e.g. Peroxigard RTU).

Waste Disposal Procedures

* Contaminated and/or potentially contaminated laboratory PPE and laboratory consumables are disposed of as biohazard waste.

Waste Disposal Procedures CONT.

* Contaminated and/or potentially contaminated bedding and PPE originating within the animal facility are bagged in red, biohazard-labeled, autoclavable bags and taped shut. Bagged cages must be autoclaved at a minimum of 121 °C, 15psi for 1 hour. Once autoclaved, bedding can be disposed of according to the [Policy on Handling Animals Exposed to Biological Hazards](https://iacuc.ufl.edu/secure/wp-content/uploads/sites/3/Policy-on-Handling-Animals-Exposed-to-Biological-Hazards.pdf).
* Unused portions of prepared cholera toxin must be inactivated with two times the volume of the toxin to be disposed of in undiluted bleach and disposed of through [UF EHS Hazardous Waste Management](https://www.ehs.ufl.edu/forms/hazardous-waste-forms/).
* Rodents euthanized or found dead prior to the clear date are identified, labeled, and disposed of according to the [Policy on Handling Animals Exposed to Biological Hazards](https://iacuc.ufl.edu/secure/wp-content/uploads/sites/3/Policy-on-Handling-Animals-Exposed-to-Biological-Hazards.pdf).

Emergency Response (Spill & Accident Procedures)

**Spills**

* If a small spill occurs inside the BSC, clean up with an approved solution (e.g. 5,000 ppm bleach solution). Collect spilled material and clean up material into appropriately labeled, nonmetallic waste container.
* For spills outside the BSC, evacuate the room for at least 30 minutes to allow dissipation of aerosols. After 30 minutes, don appropriate PPE and collect spilled material and clean up material into appropriately labeled, nonmetallic waste container.
* For large spills, call EH&S Chemical and Radioactive Waste Disposal group at 352-392-8400 for clean-up assistance.
* See [UF EHS Spill Response](https://www.ehs.ufl.edu/departments/research-safety-services/hazardous-waste-management/spill-response/#:~:text=Call%20EH&S%20Chemical%20and%20Radioactive%20Waste) for additional information.

**Needlesticks**

* Allow to bleed freely. If necessary, control bleeding by applying direct pressure with a sterile gauze or bandage.
* Immediately wash with copious quantities of soap and water.
	+ If eyes or mucous membranes are exposed, irrigate area for at least 15 minutes with water.
* Seek medical treatment.
* Report the incident to the PI/supervisor and Environmental Health and Safety (352) 392-1591 and submit an online Injury /Incident Report (<https://apps.ehs.ufl.edu/incidents/>).

Emergency Response (Spill & Accident Procedures) cont.

**If an emergency occurs outside of normal work hours, contact the University Police Department at 352-392-1111 or call 911.**

**Emergency Contact Numbers:**

* Principal Investigator: xxx-xxx-xxxx
* Lab Manager: xxx-xxx-xxxx
* Poison Control Center: 800-222-1222
* Emergency: 911
* EH&S: 352-392-1591

**Physical Address on Campus:**

[Add your lab’s address here.]

References

* [Policy on Handling Animals Exposed to Biological Hazards](https://iacuc.ufl.edu/secure/wp-content/uploads/sites/3/Policy-on-Handling-Animals-Exposed-to-Biological-Hazards.pdf)
* [[UF EHS Safety-Engineered Sharps Fact Sheet](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D)](https://webfiles.ehs.ufl.edu/Safety_Eng_Sharps.pdf#:~:text=What%20is%20a%20safety-engineered%20sharp%3F%20The%20U.S.%20Occupational,effectively%20reduces%20the%20risk%20of%20an%20exposure%20incident.%E2%80%9D)
* [UF EHS Spill Response](https://www.ehs.ufl.edu/departments/research-safety-services/hazardous-waste-management/spill-response/#:~:text=Call%20EH&S%20Chemical%20and%20Radioactive%20Waste)

Documents and attachments

List applicable forms and attachments here.