|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Protocol Information | | | | | | |
| Principal Investigator: | | |  | | | |
| Principal Investigator Phone Number(s): | | |  | | | |
| IACUC Protocol #: | | |  | | | |
| Animal Facility: | | |  | | | |
| Written and Prepared By: | | |  | | | |
| Issue Date | | |  | Revision/Review Date: | |  |
| 2. Purpose and Scope | | | | | | |
|  |  | | | | | |
| 3. Potential Hazards | | | | | | |
| Agent Description: | |  | | | | |
| Symptoms of Human Exposure: | |  | | | | |
| Dose Range: | |  | | | | |
| Route(s) of Administration:  IM  IP  IV  SQ  Intranasal  Oral  Retroorbital  Topical | | | | | | |
| Other | | | | | | |
| Frequency of Administration | |  | |  |  | |
| Agent Shedding from Animals | |  | |  |  | |
| Urine  Feces  Blood  Saliva  Respiratory  None | | | | | | |
| Other | | | | | | |
| Anticipated Half-life in Animal Model | | | | | | |
| 4. Engineering Controls Biosafety Cabinet  Cage Changing Station  Fume Hood  Downdraft Table  Ventilated Cage/Rack  Filter Top  Engineered Sharps | | | | | | |
| Other | | | | | | |
| 5. Personal Protective Equipment Safety Glasses  Face Shield  Safety Goggles  Hair Bonnet  Gown  Laboratory Coat  Coveralls  Shoe Covers  Boots  Medical Mask  N95 Respirator  Gloves | | | | | | |
| Other | | | | | | |
| 6. Medical Considerations | | | | | | |
|  |  | | | | | |
| 7. Transport of Agent/Samples Transport agent and/or samples or animals between the laboratory and animal facilities in sealed, secondary containers that are shatterproof and labeled with the appropriate hazard symbol (e.g. biohazard, chemical). | | | | | | |
| Additional information (if needed) | | | | | | |
|  |  | | | | | |
| 8. General Working Procedures  1. Wash hands with soap and water after removing gloves and after handling hazardous materials. If soap and water are not immediately available use alcohol-based hand sanitizer and follow with normal handwashing as soon as possible. 2. Change gloves frequently to avoid contamination of equipment, surfaces, and personnel 3. Use only Luer-lock syringes and needles. 4. Use safety-engineered sharps. 5. Dispose of sharps directly in sharps disposal container without recapping or other manipulations 6. Decontaminate work surfaces and equipment with approved disinfectant when work is completed and after any spill. 7. Cover spills with absorbent towels/pads and saturate with disinfectant. Do not spray disinfectant directly on spills. | | | | | | |
| 9. Experimental Procedures | | | | | | |
|  |  | | | | | |
| 10. Agent Inactivation and Disposal 1:10 Dilution of household bleach  Quaternary ammonium disinfectant  70% Ethanol  Peroxide-based disinfectant  Spor-Klenz | | | | | | |
| Other | | | | | | |
| Disposal (of agent and animal):  Sharps disposal container  Red biohazard bag  Alkaline hydrolysis (animal carcasses) | | | | | | |
| Other | | | | | | |
| 11. Exposures & Incidents If personnel experience a sharps injury or have other unprotected exposures (e.g. mucous membranes, direct contact, splash to open wounds or cuts) they should:   1. Remove contaminated clothing and/or PPE and flush mucous membranes (eyes, nose, mouth) with water from the nearest eyewash or drench hose for at least 10 minutes. Intact or non-intact skin exposures should be washed immediately with soap and water. 2. Leave the area (for inhalation hazards) and notify others. 3. Change gloves (if gloves become contaminated). 4. Perform first aid, if applicable 5. Notify supervisor and seek medical evaluation    1. Employees may seek a medical evaluation with any occupational medical practitioner    2. Students contact Cornell Health    3. All personnel (students, employees) must document exposures and injuries in the [Cornell University Incident Reporting System](https://ehs.cornell.edu/incident-reporting) (https://ehs.cornell.edu/incident-reporting) | | | | | | |
| **All-life threatening emergencies or emergencies requiring transport contact 911 from a cell phone or 5-1111 from an on-campus landline.** | | | | | | |
| **References and Miscellaneous Information** (Include web links for agent information, SDS, CARE SOPs, EHS Biosafety BARS, etc) | | | | | | |
|  |  | | | | | |
| 12. Phone Numbers Police, Fire, and Medical Emergencies: 911  Cornell Police: 607-255-5111  Environment, Health, and Safety: 607-255-8200  Cornell Health: 607-255-5155 | | | | | | |
| Principal Investigator (24 hours, 7 days): | | | |  | | |
| Principal Laboratory Contact: | | | |  | | |
| Secondary Laboratory Contact: | | | |  | | |
| Facility Contact: | | | |  | | |
| Signatures and Acknowledgement All personnel associated with this project must read, understand, and be trained to this Standard Operating Procedure. A signature acknowledges that the individual understands the hazards associated with the agents referenced in this SOP and will comply with the safe work practices described herein. Personnel must receive applicable training and be able to complete any medical consultation before handling hazardous materials and/or engaging in high-risk procedures. A copy of this acknowledgment must be kept on file with the laboratory. I hereby agree to inform the Cornell University Environment, Health and Safety of any possible occupational exposure or near miss while working at Cornell University. | | | | | | |
| Name | | Signature | | | Date | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |

# Instructions for Creating a Laboratory-Specific Standard Operating Procedure (SOP)

Start on page 1 to create your lab-specific SOP. Include relevant information from all sections. Risks should be assessed for each agent individually to determine the appropriate controls, personal protective equipment. Decontamination procedures must be in place when preparing and handling that agent. Include this SOP with any IACUC protocol application. Save with other electronic lab materials or print and place with other safety information for your lab.

# Protocol Information

Complete all fields. Since the SOP may not be accompanied by the complete IACUC protocol. This SOP can be taken to a medical care provider in case an incident does occur.

# Purpose and Scope

Describe what this agent will be used for in the lab and a brief description of work. Also, describe concentrations used and how needed concentration and amount is prepared and/or obtained. Describe **quantity** required, approximate **frequency** of use, and **location** of use. If possible, indicate that the agent will be purchased in small quantities or dilute solutions to reduce the risk of exposure and minimize waste. If this is a toxin, consider if the liquid form would be less hazardous than powder (usually depends on hazards associated with the solvent) and, if so, purchase in liquid form.

# Potential Hazards

Include the following information in this section:

* Routes of exposure (skin, inhalation, ingestion, injection); when/how exposure might occur (inhalation during weighing and mixing, splashes, needle sticks from injection preparation and administration, cleaning up spills, etc.)
* Target organs
* Information on signs/symptoms of exposure
* Toxicological data or virulence characteristics of the agent (by route of entry)

The [Toxin, Toxin-Target Database](http://www.t3db.org/) also has detailed toxin information that may help determine potential hazards. Some toxins have summary statements in the [Toxic Agent section](https://www.cdc.gov/labs/BMBL.html) of the 5th edition of Biosafety in Microbiological and Biomedical Laboratories (CDC) which may be helpful:

# Engineering Controls

List engineering controls required for this agent (e.g., Class II Type A2 or Class II Type B2 or Class III Biological Safety Cabinet, HEPA filtered enclosure inside chemical fume hood). Engineering controls should be selected according to the risk assessment for each specific agent manipulation.

*Things to consider when listing Engineering Controls for toxins (include all that apply):*

* Intentional generation of aerosols is considered a high-risk procedure that must be approved by [Biological Safety](mailto:askEHS@cornell.edu?subject=Biosafety%20-%20assistance%20handling%20aerosol%20biohazards) (607-255-8200) to ensure that adequate engineering controls are in place.
* Low molecular weight (LMW) toxin solutions or work involving radionucleotides combined with toxin solutions may require the use of a charcoal-based filter in addition to HEPA filtration.
* Work with toxins involving volatile chemicals requires a fully exhausted BSC or use of secondary containment (glove bag or box) inside a fume hood.
* The use of powdered toxins should be avoided if possible and minimized otherwise. Unavoidable operations using dry forms of toxins should be undertaken with appropriate engineering controls and/or respiratory protection. Dry toxins must be manipulated using a Class III BSC (no secondary containment required) or in a Class II BSC or fume hood with the use of secondary containment such as a disposable glove bag or glove box inside. Toxins with low LD50s or LC50s may require a respirator even when working with the powder in a BSC
* Toxins that have low toxicity should still be handled in a standard fume hood or BSC during procedures where aerosols may be produced. Aerosols may be produced during any open handling of dry powder (e.g. weighing) and during open or pressurized manipulations of suspensions.
* If powdered toxin comes in a vial with a septum, preparation of solution should occur within a standard fume hood or BSC due to possible pressure changes that may generate aerosols through the vent opening.
* Operations that expose toxin solutions or other biological agents to vacuum or pressure should always be handled inside a BSC. The operator should always use appropriate respiratory protection in case of engineering failure. Respirator users require medical clearance, training, and fit-testing. Contact EHS’s [Occupational Health](mailto:askEHS@cornell.edu?subject=Please%20help%20with%20respiratory%20protection%20program%20requirements) section at 607-255-8200 for more information on respirator use.
* If vacuum lines are used with a toxin, they should be protected by a HEPA filter to prevent the entry of toxins into the line.

# Personal Protective Equipment (PPE):

Describe additional PPE requirements for each task involving the agent. *Things to consider when listing PPE for toxins (include all that apply):*

* If the agent is suspended in solution, appropriate gloves should be worn to prevent penetration of the solvent. Solvents can act as a carrier for the toxin and can result in dermal exposure if the solvent readily penetrates the glove.
* If there is a moderate risk of cut or puncture, cut- or puncture-resistant gloves should be worn.
* When conducting liquid transfers and other operations that pose a potential splash or droplet hazard in an open-fronted BSC or hood, safety glasses, or goggles, and disposable facemask, or a face shield, must be worn.
* If working with dry forms of toxin that are subject to spread by electrostatic dispersal, static-free disposable gloves must be worn. Wetting and wiping down gloves and surfaces before beginning work can help reduce static.

Note: Respirators are masks designed to protect the wearer from specific airborne hazards and are different from surgical masks, which protect the wearer only from splashes and are primarily intended to protect others from infectious aerosols exhaled by the wearer. Respirator use requires employee participation in the Respiratory Protection Program, which involves medical clearance and annual fit testing and training. Please be clear about the use of surgical masks versus respirators. (Please do NOT use the vague term “masks”.)

# Medical Considerations

Please list vaccinations or antitoxins required or recommended for this agent.

If antitoxins or toxoid vaccinations are recommended or required, the researchers must contact Occupational Medicine at 607-255-6960 to discuss these considerations.

If there are no specific medical considerations recommended for work with the toxin, please put “No special medical considerations recommended.”

# Transportation and Storage:

Describe transportation and storage strategies taking the following information into consideration:

* Describe transportation strategy (use of secondary containers, travel through low-traffic hallways).
* Toxin solutions, especially concentrated stock solutions, should be transported in leak/spill-proof secondary containers.

# Agent Inactivation and Disposal

Describe waste disposal procedures taking the following information into consideration:

* Discarded needles/syringes and other sharps should be placed directly into properly labeled, puncture-resistant sharps containers, and inactivated/decontaminated as soon as is practical.
* Depending on the agent, contaminated materials and agent waste solutions may be inactivated by physical means (incineration or extensive autoclaving), or by chemical means (soaking in suitable decontamination solutions for a specified period). Please see Tables 1 and 2 of the CDC’s Biosafety in Microbiological and Biomedical Laboratories (BMBL) [Guidelines for Work with Toxins of Biological Origin](https://www.cdc.gov/labs/BMBL.html) for appropriate physical and chemical inactivation procedures for specific toxins. If you have specific questions about disposal, please call EHS Hazardous Materials Management at 607-255-8200.

# Exposures & Incidents

Within the references/additional materials describe any additional procedures that are specific to the agent (may be listed on Safety Data Sheet). Think about other types of emergencies that are possible and list procedures in this section for how to deal with those situations – such as how personnel may egress during a fire or other evacuation.

For additional help in completing the SOP, contact the EHS-[Biological Safety Section](mailto:askEHS@cornell.edu?subject=Assistance%20with%20an%20IACUC%20SOP) at 607-255-8200

# Document History

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Date** | **Author** | **Description of Changes** |
| 2 | September 2020 | Joshua E. Turse | Updates to sections for medical care, SOP layout. |
| 1 | July 2010 | Frank Cantone | New document |

# Document Information

CLASSIFICATION & LOCATION: Biological Safety, IACUC https://cornellprod.sharepoint.com/sites/EHSteam/bio\_safety/Biological\_Safety\_Library/IACUC SOP Template.docx