

PI Name:

Safety Protocol for Human Subjects research with **(insert name of investigational product here)**

## **Hazard Communication Statement**

Minimally include the following:

- General information about the investigational product
- Host range
- Mode of transmission
- Survival
- Potential health hazard
- include information for wildtype and recombinant microbes if applicable
- does genetic modification change host range, mode of transmission etc.?
- Who is at risk?
- Have laboratory acquired infections be reported?
- Likely symptoms of exposure as well as reasonable worst case scenarios can be included.
- Special warning should be provided for individuals who may be at greatest risk of severe complications from an exposure (e.g. immunocompromised, pregnant, etc.).
- A Material Safety Data Sheet (MSDS) for the investigational product utilized in the human subjects study should accompany the safety protocol as supplementary material.

References to support statements are encouraged.

The following links will be useful to obtain this information:

<http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php>

<http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>

Below are general precautions relevant to Biosafety Level 2. Please review to ensure that this covers your investigational product and whether additional precautions are needed.

## **2. General Precautions**

### **1. General Practices**

Precautions appropriate to a Risk Group 2 virus are recommended. Such precautions consisting primarily of **good microbiological laboratory techniques** as well as Biosafety Level 2 (BSL-2) containment. The following precautions should be employed:

- a. Access to the clinical areas with the investigational product is limited or restricted by the Principal Investigator when work with organisms containing recombinant or synthetic nucleic acid molecules is in progress.
- b. Work surfaces are decontaminated at least once a day and after any spill of viable material with 10% bleach solution.
- c. All contaminated waste including PPE is placed in red biohazard bag for disposal. Instruments used are to be sprayed with Cavicide prior to being sent for sterile processing.

- d. Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for this purpose only.
- e. Persons wash their hands: (i) after handling materials involving organisms containing recombinant or synthetic nucleic acid molecules and animals, and (ii) when exiting the clinical areas with the investigational product.
- f. All procedures are performed carefully to minimize the creation of aerosols.
- g. Clinical trials of lesser biohazard potential can be conducted concurrently in carefully demarcated areas of clinical areas with the investigational product.

## 2. Special Practices (BSL-2)

- a. Investigational product is placed in a durable leak-proof container with biohazard sticker which is closed before being removed from the investigational pharmacy and delivered to the OR.
- b. The Principal Investigator limits access to the clinical areas with the investigational product. The Principal Investigator has the final responsibility for assessing each circumstance and determining who may enter or work in the clinical areas with the investigational product.
- c. The Principal Investigator establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g., immunization) may enter clinical areas with the investigational product.
- d. When the organisms containing recombinant or synthetic nucleic acid molecules in use in the clinical areas with the investigational product require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universal biosafety symbol is posted on the access door to the clinical areas with the investigational product work area. The hazard warning sign identifies the agent, lists the name and telephone number of the Principal Investigator or other responsible person(s), and indicates the special requirement(s) for entering the clinical areas with the investigational product.
- e. An insect and rodent control program is in effect.
- f. Laboratory coats, gowns, smocks, or uniforms are worn while in the clinical areas with the investigational product. Before exiting the clinical areas with the investigational product for non-investigational product areas (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the clinical areas with the investigational product or covered with a clean coat not used in the clinical areas with the investigational product. ) Prior to leaving the OR, PPE is placed in red biohazard bag for disposal.
- g. Animals not involved in the work being performed are not permitted in the clinical areas with the investigational product.
- h. Special care is taken to avoid skin contamination with organisms containing recombinant or synthetic nucleic acid molecules; gloves should be worn when handling investigational product and when skin contact with the agent is unavoidable.
- i. All waste contaminated with investigational product are appropriately decontaminated before disposal. Prior to leaving OR, PPE will be placed in red biohazard bag which will be picked up by housekeeping. Contaminated instruments will be sprayed with Cavicide prior to being sent to sterile processing.
- j. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of fluids containing organisms that contain recombinant or synthetic nucleic acid molecules. Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use. The needle and syringe should be promptly placed in a

puncture-resistant, biohazard container which will be closed in the OR and disposed of in biohazard trash.

- k. Spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Institutional Biosafety Committee. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.
- l. When appropriate, considering the investigational product(s) handled, baseline serum samples for clinical and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically depending on the investigational products handled or the function of the facility.

3. Facilities of Clinical Areas with the Investigational product (BSL-2)

- a. The clinical areas with the investigational product are designed so that they can be easily cleaned
- b. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat
- c. The furniture of the clinical areas with the investigational product is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning
- d. Each clinical area with the investigational product contains a sink for hand washing
- e. An autoclave for decontaminating clinical areas with the investigational product waste is available

4. Investigational Product specific Practices

- a. ???

5. Use of Investigational Pharmacy

- a. List shipping and preparation requirements.
- b. List transport to clinic on day of procedure.

6. Delivery procedure

- a. List method used
- b. Safety precautions to be used, including use of needles, PPE etc.
- c. List clean up solid and liquid waste, as well as surfaces.

7. Post-administration procedures

- a. List any wound care procedures
- b. List any follow up procedures (e.g. blood draws for viral counts)

8. Outpatient Procedures

- a. List any wound care procedures
- b. List any follow up procedures (e.g. blood draws for viral counts)
- c. Risk warnings for care-takes/family members.

### 3. Emergency procedures

#### 3A. Spills of the investigational product:

- 1) Notify workers in the area.
- 2) Leave the area for 15 minutes to allow aerosols to settle. Replace contaminated PPE.
- 3) Upon return, mix spill with freshly made bleach to 10% final concentration.
- 4) Allow 30 minutes of contact time for disinfection.
- 5) Absorb spill with paper towels and dispose them into biohazard bags.
- 6) Use dustpan and broom to sweep up debris. Broken glass must be deposited into broken glass or sharps box.
- 7) Wipe the spill area clean using 10% bleach.
- 8) Dispose of contaminated PPE in autoclavable biohazard bags.

#### 3B. In the event of injury or exposure

- 1) **CLEANSE WOUND:** Wash all wounds immediately with antiseptic soap and a high volume of water for up to 15 minutes.
- 2) **CONTROL BLEEDING:** Apply bandage and firmly press to control bleeding.
- 3) **ACCIDENTAL INGESTION:** Rinse mouth with water but do not swallow.
- 4) **SEEK IMMEDIATE MEDICAL FOLLOW-UP** (*do not wait 24 hrs*)

Employees *and* students go to:

- **Employee Health Services** (during business hours: Monday-Friday, 7:30 am -4 pm).  
Address/Location: 57 Bee Street, Charleston SC 29425; Phone: (843) 792-2991
- **MUSC Emergency Room** (after business hours) Address/Location: 96 Jonathan Lucas Street, Charleston SC 29425

Be prepared to discuss the nature of the investigational product and risks of rDNA, if applicable, with the physician.

- 5) **REPORT EXPOSURE IMMEDIATELY** to the Principal Investigator and notify Biosafety Officer (843-792-3604).
- 6) **NOTIFY** Employee Health Services within 24 hours by filing a Workplace Injury form at [Care Team Member/Workplace Injury Form](#)

By signing below I attest that I have read and understood these safety instructions and agree to adhere to these rules at all times. Furthermore, I feel I have been properly notified and trained of the hazards in this laboratory.

Name (print)

Signature

\_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_ Date: \_\_\_\_\_