Title of Study

INVESTIGATIONAL PRODUCT HANDLING PLAN

**PI:**

**IRB #:**

***Occuptional Exposure Prevention & Investigational Pharmacy Procedures***

***for Protocols Using Biological or Recombinant Vectors in Humans***

**Investigational Product (IP) risk assessement.** Description. Background information. Include any medical considerations /risk to personnel preparing or administering investigational product.

**Receipt and Storage.** Manufacturer information. How shipped/stored/storage location/use.

**Aliquot Preparation and Transport.**

Investigational Pharmacy staff will wear Standard Precautions PPE (disposable gown, gloves, mask, eye protection) during investigational product preparation. All handling of the investigational product shall occur in a biosafety cabinet or a similarly contained environment.

Pharmacy Staff will observe standard sharps precautions including the following:

For syringe preparations:

To safely transport the investigational product, the needle is removed and placed in a biohazard sharps container (needle box) located in the BSC. The needleless syringe is capped by the pharmacist and packaged for transport. The entire volume of the pre-loaded syringe(s) will be prepared for delivery to administering site. PPE will be removed before transporting the investigational product. The investigational product will be transported to the study site in/by \_\_\_\_\_\_\_\_ and in a rigid secondary container. Pharmacy staff will decontaminate the BSC using standard procedures.

Preparation will take place in a Class II Biological Saftey Cabinet (BSC) in a designated hazardous drug preparation room as defined by USP 800. The BSC that will be utilized is located at Investigational Drug Service (IDS) pharmacy. During the time that preparation is in progress, access to the immediate area will be limited to only those personnel requiring access. Prior to preparing the gene therapy product, the BSC will be decontaminated with an appropriate agent, such as 10% (v/v) bleach solution or virucide and wiped with 70% isopropyl alcohol. Absorbent pads will be placed in the BSC for use during gene therapy preparation. A spill kit and a bottle of disinfectant (bleach) will be kept near the BSC during preparation for decontamination or spills. Gene therapy agents must be prepared by a trained pharmacist and the process double checked by a second pharmacist.

During preparation, Investigational Pharmacy staff will wear protective equipment including a disposable gown, two pairs of chemotherapy gloves, mask, and a hair cover. The glass shield of the BSC will be lowered to protect the eyes. A small sharps container will be placed inside the BSC for disposal of all study product waste and sharps during preparation. In the BSC, the appropriate administration set will be attached and primed.

To safely transport the investigational product, the needle is removed and placed in a biohazard sharps container (needle box) located in the BSC. The needleless syringes are capped by the pharmacist using the polypropelene cap supplied by the sponsor and packaged for transport. The entire volume of the pre-loaded syringe(s) will be prepared for delivery to administering site. PPE will be removed before transporting the investigational product. Hand washing will take place prior to leaving the clean room. The investigational product will then be **transported in a leakproof secondary container with absorbent material labeled with a biohazard symbol** to the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Pharmacy staff will decontaminate the BSC using standard procedure.

**For IV bag preparations:**

Investigational Pharmacy staff will wear Standard Precautions PPE (disposable gown, gloves, mask, hat and footcovers) during investigational product preparation according to USP <797> guidelines. All handling of the investigational product shall occur in a biological safety cabinet. A small sharps container will be placed inside the BSC for disposal of all study product waste and sharps during preparation. In the BSC, the appropriate administration set will be attached and primed. The port on the IV bag is covered before removing from the BSC. Pharmacy staff will decontaminate the BSC using standard procedure. PPE will be removed before transporting the investigational product.

The infusion bag containing the study drug will be transported to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ by The Department of Pharmacy Investigation Drug Services in a rigid, leakproff secondary container labeled with a biohazard symbol.

**Administration.**

A full face-shield or safety glasses with surgical mask will be worn in addition to Standard Precaution PPE by clinical staff administering the investigational product. A sterile capped needle is placed on syringe.

Personnel will follow the standard DUH hygiene precautions where patient care is taking place. Any potentially contaminated surface will be cleaned using a DUH approved disinfectant. Appropriate hand hygiene is required before and after any handling of the investigational product.

**Disposal.** All surgical materials used in the procedure and (potentially) that come in contact with the investigational product are disposable. These materials, including disposable PPE will be placed in biological waste containers for disposition using established DUH procedures. Used sharps will be disposed in biohazard sharps container (needle box).

**List of locations.**

* (receipt and storage,
* aliquot preparation and storage)
* (Study site) and (drug administration setting)
* other

**Spill procedures.** Cleaning must be done while wearing PPE including, but not limited to chemically resistant gloves, as well as safety glasses, gowns, and lab coats. In case of an accidental spill, the investigational product is inactivated with an EPA-approved hospital tuberculocidal or mycobacteriocidal disinfectant or a freshly-prepared diluted bleach solution (1:10 bleach:water). Wipe the spill with absorbent towels to remove the spill. Place the towels in biohazard waste. Cover the area with disinfectant, wait 20 min or effective time noted on disinfectant label and wipe away with more absorbent towels. Place towels in biohazard waste**. Any spill of the investigational product that has an environmental impact must be reported to OESO-Biological Safety Division (919-684-8822) for review.**

**Medical Considerations for Occupational Exposures:**

**Exposure Procedures.** Any potential exposures will be reported immediately by calling the exposure hotline (919-684-8115). Employee Occupational Health and Wellness (EOHW) will evaluate each exposure and develop an appropriate response. **Any accidental exposure to the investigational product will be reported to the OESO-Biological Safety Division (919-684-8822) who will report to NIH according to the NIH rDNA Guidelines.**

* ***Eye exposure from splash or aerosol***

Rinse a minimum of 15 minutes in eye wash or flush with water. Immediately notify Employee Occupational Health and Wellness by dialing 115 from a Duke Phone or 919-684-8115 from any phone.

* ***Needlestick, sharps exposure, or non-intact skin exposure*** Contaminated skin must be washed with soap and copious amounts of water. Immediately notify Employee Occupational Health and Wellness by dialing 115 from a Duke Phone or 919-684-8115 from any phone.