**Institutional Biosafety Committee – Site-Specific Biosafety SOP**

**[Enter location (E.g., Children’s Hospital of Colorado)]**

**IND [enter name of IND]**

**Clinical Trial IRB number: [enter number]**

**Principal Investigator: [enter name]**

**Sponsor: [enter name]**

**Version [enter version number (E.g., 1)], dated [enter date]**

1. **Product Name & General Information:** [enter IND name]; [Include general information about the study agent. For example – AAV8 vector containing codon optimized, wild-type human glucose-6-phosphate (G6PC) gene for the treatment of patients with glycogen storage disease type 1a (GSDIa).]

# RISK INFORMATION:

* 1. **Routes of Exposure:** Possible routes of inadvertent exposure to [enter IND name] include sharps injuries (needlestick, etc.) and contact with skin or eyes.
	2. **Pre-exposure Requirements/Recommendations:** [enter details (E.g., There are no pre-exposure vaccinations or tests recommended specifically for staff involved with handling {Enter IND name}).]
	3. **Anticipated Effect of Exposure (for Study Staff):** Although study staff may not be exposed to the entire amount of the subject dose, anticipated effects of exposure to staff handling [enter IND name] may include [list potential side effects].
	4. **Staff Restrictions:** Members of the study staff who have concerns regarding working with the study agent are encouraged to self-identify. In addition, without revealing personal health information, staff can discuss confidential occupational health concerns with an appropriate healthcare professional per Institutional policy or their personal primary healthcare physician, who can implement or recommend any necessary accommodations. Staff may decline to handle the study agent at any time without specifying a reason and with no negative consequences.

All personnel must be clearly trained on safety measures per study documents (such as the pharmacy manual & protocol), as well as this SOP and other institutionally required SOPs.

# STORAGE AND HANDLING OF [INSERT IND NAME]:

* 1. **Biohazard Signs:** When the study agent is in storage or being handled, a biohazard sign will be posted at the entrance to any room used and approved on the protocol. Approved spaces are listed on the Institutional Biosafety Committee (IBC) protocol.
	2. **Personal Protective Equipment (PPE):** The following PPE, at a minimum, must be used when handling [enter IND name] and any biohazardous material:

# Preparation:

[ ] GLOVES [ ] GOWN [ ] MASK [ ] EYE PROTECTION

# Dosing:

[ ] GLOVES [ ] GOWN [ ] MASK [ ] EYE PROTECTION

# Spill Clean-up:

[ ] GLOVES [ ] GOWN [ ] MASK [ ] EYE PROTECTION

* 1. **Preparation:** [Describe how the IND will be prepared, including which procedures are performed inside a biosafety cabinet.]

# Study Agent Transportation:

* + 1. **Internal Transport:** The study agent will be transported between handling locations inside a rigid, leak-proof container labelled with a biohazard sticker on the outside. If the study agent is removed from its original sponsor packaging, it will be placed inside of a Ziploc-style bag as an additional form of containment prior to transport.
	1. **Dosing:** Study personnel must be trained according to the protocol, pharmacy manual, sponsor, & site-specific requirements for dosing. Please see IBC approved document versions for details.
	2. **Decontamination (after study agent handling):** Work surfaces will be decontaminated with either 10% freshly prepared bleach solution (1 part household bleach and 9 parts water) or [enter disinfectant used] with a wet contact time of 10 minutes and 2 minutes, respectively.
1. **BIOHAZARDOUS WASTE DISPOSAL:** Biohazardous waste bins are available in all areas where the study agent is handled. All disposable material that potentially comes into contact with [enter IND Name], including PPE, will be discarded as biohazardous waste. Full biohazardous waste containers are collected and decontaminated off- site by a licensed biohazardous waste company.
	1. **Storage and Disposal of Study Agent Vials:** Study agent vials will be placed in an appropriately labeled, rigid, leak-proof container and stored in the Storage Room until disposal or return to the Sponsor.

# SPILLS and EXPOSURES:

* 1. **Spills:** Only trained study staff members are allowed to decontaminate spills of the study agent. In the event there is an accidental release of [enter IND name]:
1. If the spill is outside of containment, stop, notify others, and isolate the area.
2. Put on appropriate PPE as listed in section 3.2, if not already worn.
3. Remove any broken glass or sharps with a forceps or other applicable tool, and place into a sharps container.
4. Overlay the spill with [enter specific disinfectant name] to cover the spill.
5. Allow the wipe to stand for a wet contact time of 2 minutes.
6. Dispose of the contaminated wipe into a biohazardous waste container.
7. Clean up any remaining disinfectant with another wipe.
8. Discard all material, including PPE, into designated biohazardous waste containers.
9. Immediately after completing the clean-up, notify the Principal Investigator and staff members as required per institutional policy.
	1. **Exposures:** In the event that there is an accidental exposure to [enter IND name]:
10. Dispose of contaminated PPE into a designated biohazardous waste container.
11. **For Skin Contamination:** Wash the affected area immediately and thoroughly using soap and water.
12. **For Needlestick Injury:** Wash the affected area immediately and thoroughly for 10 minutes using soap and water. Cover with a sterile gauze dressing which must be discarded into a biohazardous waste container when removed.
13. **For Eye Contamination:** Rinse the affected eye thoroughly for 10 minutes using an eyewash, making sure that the water flows across the affected eye is from the nose to the outer corner of the eye. If only one eye is affected, avoid contaminating the other eye (the affected eye must be below the other eye). Maintain the eyelids open and ask the exposed person to look up, down, and sideways, thus more fully exposing the eyeball to the wash. In the event of an eye exposure, the exposed individual should be referred to a healthcare professional (eye doctor).
14. After completing first aid measures, notify the Principal Investigator and other staff members as needed per Institutional policy. In the event of an “overt exposure”, the Principal Investigator is required to notify the Sponsor, the IBC and NIH Office of Science Policy (OSP). The exposed staff member should be referred to an appropriate healthcare professional according to Institutional policy.