**University of Miami**
**Institutional Biosafety Committee (IBC)**
**Site-Specific Biosafety Standard Operating Procedure**
**for the Safe handling of study Biological Agents (viral constructs)**

A Biosafety SOP is required for all Human Gene transfer studies at the University of Miami Please fill out this form and send this (with all other documents required on the Human Gene Transfer Checklist) to IACUCsupport@med.miami.edu. Bio-containment at the respective biological agent Biosafety level must be replicated at all steps of the process.

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| **PI Name:** | |
| **Date:** | |
| **Title of Study**: | |

## Section 1: Introduction and Purpose of Work:

***Provide a brief description of the study AND the biological agent (viral construct).***

## Section 2: Study-related activities at UM *(check all that apply):*

- ☐ **Synthesis and/or production of biological agent**
- ☐ **Shipping or receiving of biological agent**
- ☐ **Biological agent storage**
- ☐ **Biological agent administration**
- ☐ **Disposal of used vials/unused biological agent**
- ☐ **Biopsy post biological agent administration**
- ☐ **Collection of subject samples post biological agent administration (blood, urine, sputum, stool, saliva, etc.)**
- ☐ **Follow-up visits**

## Section 3: Handling of the Biological Agent information at UM

***a)*** **What are the storage conditions of the agent?** (*Please indicate how the agent is shipped and then stored at UM; for example, shipped frozen -20 degree ± 5C, dedicated and/or restricted freezer).*

***b)*** **Where is the Storage location(s)?** *(provide the location in the pharmacy, building and room numbers)*

***c)*** **How is the agent prepared?** *(provide all details of the preparation, including Biosafety cabinet used, description of the dosing container, indicating that it capped and labeled for transport)*

***d)*** **Describe how the agent will be contained and transported from time of receipt to administration to the patient to prevent spills or accidental exposures.**

***e)*** **Describe the physical route that agent will take (e.g. from receipt to administration of agent), indicating the specific buildings and rooms.**

***f)*** **Is the biosafety cabinet certified? Please provide the Company used for the certification and the latest date done.**

***g)*** **What Personal Protective Equipment (PPE) will be used during preparation of the agent?**

***h)*** **Where are the eyewash stations located in each area that the agent will be handled?**

## Section 4: Gene Transfer subject administration and monitoring area

***a)*** **Where is the location(s) of the agent administration?** *(provide building and room numbers and whether the room is carpeted)*

***b)*** **What PPE will be used during administration of the agent?** (include the safety needles and safety engineered devices used)

***c)*** **What is the route of administration?** *(Orally, intravenously etc.)*

***d)*** **Describe how spills are contained and decontaminated and provide product name used for decontamination.**

***e)*** **Describe how work surfaces are decontaminated and provide product name used after each inoculation of subjects.**

## Section 5: Viral Gene Transfer information to patients, family, and UM staff *(Fill out Section 5 for viral gene transfer protocols only)*

***a)*** **Describe how the subject is separated from the non-study staff and patients.** *(consideration should be given to procedures occurring in nearby areas and/or compromised patients)*

***b)*** **What is the process to communicate and/or educate the subject, family or close contacts about the precautions for isolation or containment AFTER administration of the study agent (e.g., viral shedding)?**

***c)*** **What is the process to communicate and/or educate the subject, family or close contacts about any precautions during follow-up visits AFTER administration of the study agent (e.g., viral shedding)?**

***d)*** **What is the process to educate pathology, autopsy and hospital staff regarding required precautions if the patient is hospitalized or die AFTER receiving the study agent (e.g., viral shedding)?**

## Section 6: Gene Transfer product shipping and receiving information

***a)*** **Describe how the leftover investigational agent will be shipped back to the Sponsor and indicate that every staff member shipping agent has current DOT/IATA certification in the shipping and receiving hazardous materials.**

## Section 7: NIH Guidelines Administrative information *(**ALL** items listed below in this section must checked and completed prior to approval)*

- ☐ **The PI has read the November 2013 revision of the NIH Guidelines for Research Involving Recombinant DNA (NIH Guidelines) and a copy is on site.**
- ☐ **A copy of the 5th edition of the Biosafety and Biomedical Manual (BMBL) is on site.**
- ☐ **Protocol-specific training is complete and documented.**
- ☐ **Required OSHA and BBP Training is current (on hire and annually thereafter) for those handling the study agent.**
- ☐ **Required Biosafety Training is current (on hire and every three years thereafter) for those handling the study agent.**
- ☐ **Required Shipping Dangerous goods Training is current (on hire and every two years thereafter) for those receiving or shipping the study agent.**
- ☐ **Study staff and PI are aware of the reporting responsibilities for Serious Adverse Events and research related Incidents (needle sticks, spills, exposure, etc).**
- ☐ **Spill and exposure plans specific to the biological agent is readily available.**
- ☐ **Biohazard signs (available from UM EHS) is posted on freezer/storage unit, entry door where the agent is prepared and administered when activities are in process. The sign includes biosafety level, PI name & emergency contact numbers, required PPE and entry requirements.**
- ☐ **A UM site-specific biosafety manual is available and contains general information on:**
  - **biological agent**
  - **routes of exposure-related transmission**
  - **signs and symptoms of exposure,**
  - **list of PPE,**
  - **Biomedical waste handling SOP**
  - **Spill and exposure plan**
  - **aerosol control procedure**
  - **exposure follow-up plan**
- ☐ **Relevant staff have received recommended vaccinations specific for the agent, or have signed a declination form.**
- ☐ **If you are using any other recombinant agent(s) on site, it must be isolated or stored separately as well as the subjects for that part of the study.**

## Section 8: Training of Personnel

**Identify the personnel and the roles of each individual who will be handling the study agent. Indicate their specific biosafety training and the years of experience doing procedures that are relevant to the study procedures** *(Include biological Safety training, Laboratory Safety training, OSHA and BBP)*

| Full Name | Degree | Biosafety Training | Describe experience with procedure(s) | Years of experience | Project Responsibilities |
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