

DARTMOUTH COLLEGE

Biological Safety Program

Institutional Biosafety Committee

for Clinical Gene Therapy (IBC-CGT)

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| Local Safety Standard Operating Procedure (SOP) |
| For Clinical Gene Transfer Research Protocols |

*Date completed:*

**I. General Information**

Principal Investigator:

Study Title:

Sponsor:

Sponsor Protocol #:

Local Study #:

IRB Protocol #:

IRB Approval Date:

Primary Site:

**2. Description of Study Agent** (brief description of recombinant or DNA characteristics of study agent, such as vector backbone, transgene, etc):

**4. Emergency Contacts** (in the event of spills, accidental exposures, or other environmental or safety concerns; add more roles if needed):

**Role Name Phone Email**

**Principal Investigator:**

**Subinvestigator:**

**Nurse Coordinator:**

**Study Coordinator:**

**Investigational Pharmacy:**

**DHMC Safety Manager:**

**Dartmouth Biosafety:** Caitlyn Hauke, PhD (603) 646-2182 biosafety@dartmouth.edu

**IBC-CGT Chair:** Lionel Lewis, MD (603) 650-7811 lionel.lewis@dartmouth.edu

**Medical Monitor:**

**Sponsor After Hrs Contact:**

**Alter. After Hrs Contact:**

**5. Training Requirements** (i.e., BSL2, blood-borne pathogens, etc):

**6. Shipping of Study Agent** (describe how the agent will be shipped, received, unpacked):

**7. Storage and Security of Agent** (describe how and where the agent will be stored before and after preparation):

**8. Inventory of the agent** (describe how the quantities of the agent will be monitored):

**9. Handling and preparation of the study agent** (describe how the agent will be prepared and the precautions taken to reduce potential exposures):

**10. Transport of study agent** (describe how the agent will be transported from the investigational pharmacy to the site of administration):

**11. Administration and disposal of the study agent** (describe who will administer the agent, the precautions taken during handling and administration, and how any remaining agent will be disposed):

**12. Facility guidelines for administration** (location, sign postings, decontamination procedures):

**13. Outline accidental spill clean-up procedure:**

**14. Outline accidental exposure response** (i.e., skin, mucous membranes, inhalation, needlestick, ingestion, etc):

 *a. Immediate first aid procedures:*

 *b. Reporting procedures:*

**15. Identify risks of exposure of clinical staff to agent from study subjects and/or their excretions:**

**16. Training of personnel** (who, type of training, maintenance):