Local Standard Operating Procedure (SOP) for Conducting a Clinical Gene Transfer Research Protocol

## LOCAL SOP VERSION DATE:

## PRINCIPAL INVESTIGATOR:

## STUDY TITLE:

## SPONSOR PROTOCOL NO:

## VELOS PROTOCOL NO:

## PROTOCOL VERSION DATE:

## SPONSOR:

## STUDY SITE(S):

### Description of Study Agent:

### General Handling Information:

### Emergency Contacts:

Use this list in the event of spills, accidental exposures or other environmental or safety concerns.

(List Name and Contact Information of Personnel Listed Below):

#### INVESTIGATOR:

#### SUBINVESTIGATOR:

#### SUBINVESTIGATOR:

#### SUBINVESTIGATOR:

#### NURSE COORDINATOR:

#### STUDY COORDINATOR:

#### INVESTIGATIONAL PHARMACY:

#### HOSPITAL SAFETY MANAGER, BIOSAFETY AND ENVIRONMENTAL PROGRAMS:

#### MEDICAL MONITOR:

#### SPONSOR AFTER HOURS CONTACT:

#### BACK UP AFTER HOURS CONTACT:

## Training Requirements:

## Shipping of Study Agent:

## Storage and Security of Study Agent:

## Inventory of the agent:

## Release of the agent for administration:

## Handling and preparation of study agent:

## Transport of study agent:

## Administration of study agent (Guidelines for administration to study subjects):

## Administration Guidelines (Guidelines for facility requirements during administration (location, sign postings, decontamination procedures)):

## After the administration of the test article:

## Clean-up procedure for an accidental spill:

## Accidental exposure (i.e., skin, mucous membranes, inhalation, ingestion) to the agent:

#### Provide immediate first aid:

#### Reporting:

## Risks of exposure to study subjects or their excretions:

## Maintenance of local records of personnel training:

## References and for more information: