UNIVERSITY OF MIAMI INSTITUTIONAL BIOSAFETY COMMITTEE

Human Subjects Annual Report/Closure form

Please attach a copy of the updated clinical protocol including a technical abstract

Principal Investigator:
Department:
Primary Contact:
IBC Protocol #:
Sponsor:

Email:
Date of Initial IBC Approval:
Grant #:
FDA IND Application #:

Title of Project:

Purpose of Study (Please explain in lay terms and without acronyms

A. Annual report of IIIC clinical trials: Progress Report and Data Analysis. Information obtained during the previous year's clinical and non-clinical investigations

1. Who is the participant population (such as disease indication and general age group, e.g., adult or pediatric)

2. What is the total number of participants planned for inclusion in the trial?
3. What is the total number entered into the trial to date the number?
4. What is the total whose participation in the trial was completed?
5. How many patients have been treated?
6. What is the number who dropped out of the trial? Provide a brief description of the reasons below:

7. **Did any of the patients experience any adverse events related to this protocol?** YES

8. **If yes, attach a summary of all serious adverse events submitted during the past year providing the following:**
   a. a narrative or tabular summary showing the most frequent and most serious adverse experiences by body system
   b. a summary of all serious adverse events submitted during the past year
   c. a summary of serious adverse events that **were expected** or **considered to have causes not associated** with the use of the gene transfer product such as disease progression or concurrent medications;
   d. if **any deaths have occurred**, the number of participants who died during participation in the investigation and causes of death; and
   e. a brief description of any information obtained that is pertinent to an understanding of the gene transfer product's actions, including, for example, information about dose-response, information from controlled trials, and information about bioavailability.

9. Indicate the Biosafety level of this study: BL-1

10. What is the status of the trial? Open *If closed please fill out section B below.*

11. Did the IND change or have any changes been made to the protocol since the last IBC review? (new vectors, new cDNAs, changes in rDNA, changes in laboratory rooms, changes in procedures for using biohazardous agents, etc.) NO

If yes, please describe here and list the date of IBC approval.

Description of Changes	**Date of IBC Approval**

If you are requesting to make a change at this time, please submit the IBC amendment form in addition to this form.

B. This section is for the closure of IIIC studies only.

1. Please provide the official date of the closure (i.e., the study is not following up on any subject nor collecting any additional data)

2. Was a final report submitted to the Sponsor? NO

   a. If so, please provide date of submission and attach the close out notification from the Sponsor

   Please provide a brief description of any study results below:

Are there any publications related to this study? If so, please attach.

Principal Investigator's signature

Print Name **Date**

Please email this form AND submit one signed copy to IACUCsupport@med.miami.edu for IBC review.

Revised 5-2-17