Subject: Procedure for Reporting of Serious Adverse Events and/or Unanticipated Problems Involving Risk to Participants or Others to the Institutional Biosafety Committee for Human Subjects

Procedure:
This procedure outlines the process for reporting serious adverse events and/or unanticipated problems to participants or others involved in human subjects research in which an IBC-HS governed biologic was involved. For the purposes of this policy Serious Adverse Events are event that result in death, a life-threatening event, an in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

I. Investigator Responsibilities.

A. It is the responsibility of the Investigator to submit, in accordance with Appendix M-I-C-4, a written report on any SAE that is both unexpected and associated with the use of the recombinant or synthetic nucleic acid product. The report must be clearly labeled as a “Safety Report” and must be submitted to the NIH OSP and to the VUMC IBC-HS within the timeframes set forth in Appendix M-I-C-4-b. Copies of any follow-up communications between the PI and OSP regarding the reported SAE should be submitted to the IBC-HS.

B. It is the responsibility of the Investigator to report all adverse events and unanticipated problems involving risk to participants or others receiving gene transfer under an IBC-HS application according to HRPP Policy III.L.

C. It is the responsibility of the Investigator to report all adverse events and/or unanticipated problems involving risks to participants or others determined to be “probably attributable” to the IBC-HS as soon as possible, but no later than 7 calendar days after the Investigator first learns of the event or problem.

D. Prior to and at the time of IBC-HS continuing review of an approved research study, it is the Investigator’s responsibility to keep the IBC-HS informed for the accurate documentation, investigation, and follow-up of all possible study-related adverse events and/or unanticipated problems involving risks to participants or others.

E. Investigators are responsible for informing all sponsors of any adverse events and/or unanticipated problems involving risks to participants or others in accordance with the Federal regulations and Institutional policies and procedures including the IRB.

F. Investigators are responsible for informing the appropriate Institutional Committees of any adverse events and/or unanticipated problems involving risk to participants or others in accordance with the federal regulations and Institutional policies and procedures including the IRB.
II. IBC-HS Committee Responsibilities.

A. All reported adverse effects and/or unanticipated problem involving risk to participants or others associated with the use of an investigational drug in a research study will be reviewed by the IBC-HS at the earliest convened meeting. The IBC-HS will evaluate the following factors for determining its recommendation:
   1. The seriousness of the event;
   2. The relationship of the event to study participation;
   3. The relationship of the event to the use of the agent; and
   4. Whether the Investigator is responsible for the reporting of adverse events and/or unanticipated problems involving risk to participants or others to a regulatory agency.

B. All serious and unanticipated adverse events or unanticipated problems involving risk to participants or others will be submitted to the Chairperson or his/her designee for an expedited or referral to the full IBC-HS/IRB for a determination.

C. The IBC-HS/IRB may render the following determinations:
   1. Accept the adverse event or unanticipated problem involving risk to participants or others without revision to the study application or related documents;
   2. Accept the adverse event or unanticipated problem involving risk to participants or others, but make recommendations to minimize reoccurrence and revisions of related documents;
   3. Accept the adverse event or unanticipated problem involving risk to participants or others, with revision and re-consenting of current participants and/or notification of participants that might be affected that have ended participation; or
   4. Suspend the study.

D. The IBC-HS may recommend termination of the study to the IRB, providing a rationale to the IRB and the Investigator (See HRPP Policy II.B).

E. The IBC-HS must immediately report all adverse events and unanticipated problems involving risks to participants or others determined by the IBC-HS to be “probably attributable” to the use of an IBC-HS governed drug in a research study to the NIH, FDA, and any other appropriate federal agencies.