Serious Adverse Event Reporting Form
Gene Transfer Protocol

Reporting of serious adverse events to the FDA, NIH OBA/RAC, the UVA Human Investigation Committee (HIC) and the UVA Institutional Biosafety Committee (IBC) is a critical element of the Federal and Institutional oversight of human gene transfer research. This form is provided to facilitate complete and standardized adverse event reporting.

A **Serious Adverse Event** is defined as:

"any expected or unexpected adverse event, related or unrelated to the intervention, occurring at any dose that results in any of the following outcomes; death, a life-threatening event, in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization also may be considered a serious adverse event when, based upon appropriate medical judgement, they may jeopardize the human gene transfer research subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition."

Submit the following pages of this form within 24 hours:

- HIC and IBC: Page 2 and 3
- NIH OBA/ RAC: Page 3
- FDA: Page 3

Contact Information:

HIC	Phone: 804-924-9634 FAX: 804-924-2932	Barringer Room 4361 or P O Box 800483 UVA Health System Charlottesville, Virginia 22908
IBC	Phone: 804-982-1597 FAX: 804-982-1590	Jordan Hall, Room 7-85 UVA Health System Charlottesville, Virginia 22908
FDA	Phone: 301-594-5400 FAX: 301-594-6197	Food and Drug Administration Center for Drug Evaluation and Research 5600 Fishers Lane Rockville, Maryland 20857
OBA/RAC	Phone: 301-496-9838 FAX: 301-496-9839	NIH, MSC 7010 6000 Executive Blvd, Suite 302 Bethesda, Maryland 20892-7010

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HIC Protocol #_____ **IBC Protocol#_____**

Subject Identifier (Do not use name)_____ **Sponsors SAE ID#_____**

Initial Report_____ or Follow up #_____ **Date of Serious Adverse Event (SAE)_____**

Brief SAE Description: _____

SAE occurred in protocol at: (Circle One) UVA Other U.S. Site Foreign Site Unknown/Not at UVA

Date SAE Report Submitted to:

HIC:_____ IBC:_____ OBA/RAC:_____ FDA:_____

1. Are any changes required in the informed consent/assent form(s) to better inform and protect the rights of the subjects? If the answer is no, provide a brief rationale. YES NO

2. Is it necessary to repeat the informed consent discussion with subjects who have already agreed to participate in the study? If the answer is no, provide a brief rationale. YES NO

If the answer to either of the questions is yes, submit two copies of the revised consent/assent form. One copy should have the changes highlighted.

Signature of Principal or (*Sub Investigator) _____ Date_____

Return Receipt Acknowledgement to _____ Phone_____

By: Pick up Box _____or Messenger Mail Box# _____ **Date Submitted to HIC: _____**

* Only if PI is unavailable to sign for 24 hour notification.

For use by the Office of the HIC Committee

Date of Receipt:_____ Received by:_____

Additional HIC review required? YES Full Board Date_____ NO-Expedited

Reviewed by HIC QA Director _____ Date_____

Reviewed by HIC Chair or Vice Chair _____ Date_____

Reported to Dean/department head? YES NO

If yes: Reported to _____(Attach Correspondence)

Review Complete on: _____ By_____

Date Entered in Database :_____ By:_____

Receipt Acknowledgment Sent on _____ By _____

For use by the Office of the IBC Committee

Date of Receipt:_____ Received by:_____

Reviewed by IBC Chair or Vice Chair _____ Date_____

Receipt Acknowledgment Sent on _____ By _____

OBA/RAC Serious Adverse Event Report Form

Instructions: Use your word processing program to fill in the requested information within each category. In order to ensure complete reports, it is important that all data fields are completed. Current institutional contact information is required. Return the form to OBA/RAC by fax, or post. This information is subject to FOIA, therefore, omit all patient identifiers and proprietary information. Please contact the OBA/RAC if there are any questions. Note that this form will be updated periodically. (Version 11-22-99)

NIH PROTOCOL NUMBER (This number consists of a four digit year/month identifier followed by a three digit sequence number)
FDA IND NUMBER (This number has four digits)
CLINICAL TRIAL SITE Name of Institution, Street Address, City and State
IND Sponsor
IBC Chair Name: Date Reported:
IRB Chair Name: Date Reported:
Principal Investigator(s)
Vector Type (e.g., adenovirus)
Vector Sub-Type (e.g., type 5—also include relevant deletions)
Gene Delivery Method
Route of Administration (e.g., injection + site)
Dosing Schedule and Treatment Group Criteria
Patient Data:
Date of Adverse Event
Complete Description of the Event
Suspected Cause of the Event
Relevant Clinical Observations (For example there are 24 standard pathophysiological/anatomical categories with defined grades of severity from 0 to 5. See also Common Toxicity Criteria (CTC) at http://ctep.info.nih.gov/CTC3/Download/ctc_gendatacol.doc
Relevant Clinical History
Relevant Tests (That have been conducted to date) (That will be conducted)
At this time is the event considered: RELATED POSSIBLY RELATED NOT RELATED to administration of the gene transfer product?
Any similar observations in other patients treated in this study or a similar study?
In the event of death, has an autopsy been requested? If not, why not?