UK Internal Prompt Reporting Form

PI Name:		IRB Protocol #:		IBC #:	
Title of Study:					

Use this form to report *Internal* **Unanticipated Problems Involving Risks to Subjects or Others** and **Research-Related Deaths** to the Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC). Please do not use this form if the event occurred with research subjects in multi-center research projects that do not fall under purview of UK IRB ("external"). For external reports use the *UK External Prompt Reporting Form.*

Refer to the *UK IRB Policy on Unanticipated Problem and Safety Reporting* to determine which events meet the reporting criteria and the required timeframe for reporting.

INSTRUCTIONS: Complete all applicable items. If items do not apply to your research, insert "N/A" (Not Applicable). Attach any supporting documentation. Remove subject identifiers from documentation and replace with participant's study identification number/code.

Submit to: **IRBSubmission@uky.edu**

or IBC: electronically to Brandy Nelson at brandy.nelson@uky.edu

STUDY and REPORT INFORMATION:

PI Telephone Number: _____

PI E-mail Address: _____

Name of Clinical Trial Site/Organization: *University of Kentucky*

Reports submitted to (check all that apply):

- ☐ UK IRB
- ☐ UK IBC: Submit if biohazardous materials or Recombinant DNA used
- ☐ FDA, if applicable
- ☐ Sponsor, if applicable

Project is extramurally funded:

- ☐ Yes If yes, list agency(ies)/sponsor(s): _____
- ☐ No _____

Reporter name: _____

Reporter phone number: _____

Reporter E-mail address: _____

Date this report completed: _____

NIH/OBA (RAC) Protocol Number (if applicable): _____

FDA IND Number (if applicable): _____

FDA IDE Number (if applicable): _____

Optional (If you need the special reference numbers in the IRB approval letter, complete this box.)
Site Adverse Event #:
Sponsor's Identifier:

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PROBLEM / ADVERSE EVENT (AE)

Check the applicable boxes for the problem/adverse event:	
1. ☐	The problem/adverse event suggests that the research places subjects at a greater risk of harm than was previously known or recognized (including physical, psychological, economic, or social harm); **and**
2. ☐	The problem/adverse event was unexpected; **and**
3. ☐	The problem/adverse event is related or possibly related to participation in the research.
4. ☐	The problem/adverse event involves a death which is related to participation in the research.
5. ☐	The problem/adverse event does not fall under the IRB's prompt reporting requirements, but **in the PI's judgment**, prompt reporting of the event(s) is in the best interest of the subject (s) because it may affect the safety and/or welfare of subjects and/or change the risk level of the study.

Type of Report: ☐ Initial ☐ Follow-Up

Research participant's study identification number/code: _____

Problem/AE Onset Date: _____ Problem/AE Termination Date: _____

Event occurred at: ☐ UK ☐ Other (specify): _____

Research participant's gender: ☐ M ☐ F

Research participants age: _____

Description of Event (include time relationship to research interventions):

Action/treatment taken in response to Problem/AE (include dates and treatments):

Relevant tests (e.g. x-rays) and results:

List names of concomitant medications:

Describe pre-existing conditions/relevant clinical history:

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List documentation accompanying this report (e.g. progress notes, discharge summary, etc.):

Prisoners: If the problem/adverse event involves a **prisoner**, indicate whether the prisoner was a patient in the University of Kentucky Medical Center at the time of the event. If the prisoner was not a patient at UK, describe how the study investigator was involved in the care during the event:

Seriousness of the Problem/AE (check all that apply):	☐ Death* ☐ Life-threatening* ☐ Initial or prolonged Hospitalization* ☐ Disability* ☐ Congenital anomaly* ☐ Required intervention to prevent permanent impairment/damage* ☐ Other medically important event* ☐ Financial Harm ☐ Emotional/Psychological Harm ☐ Other *FDA: What is a Serious Adverse Event?
Outcome of the Problem/AE:	☐ Recovered/resolved ☐ Recovering/resolving ☐ Not recovered/not resolved ☐ Recovered/resolved with sequelae ☐ Fatal ☐ Unknown ☐ Other _____
Problem/AE Attributed to:	☐ Study medication ☐ Underlying disease ☐ Errors in study medication administration ☐ Breach of Confidentiality ☐ Device Failure ☐ Social Science/Education Interventions ☐ Protocol deviation / exception / violation ☐ Concomitant medication ☐ Medical Intervention ☐ Route of administration ☐ Invasion of Privacy ☐ Other suspected cause (describe on separate sheet) ☐ Research Subject Complaint (describe on separate sheet)

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Has the same Problem/AE occurred previously in this study?	○ Yes ○ No	If yes, how many times?:_____

If death, date of death: ___/___/___ If a subject death, was autopsy performed? ○ Yes ○ No ○ N/A

Date of autopsy: ___/___/___

STUDY TEST ARTICLES, IF APPLICABLE

What study test article was administered/received?	☐ Approved Drug ☐ IND agent ☐ Placebo ☐ N/A ☐ Other: Describe: _____	☐ Approved Device ☐ IDE agent ☐ Blinded Study Agent
Was the administration of the test article stopped because of this Problem/AE?	○ Yes ○ No ○ N/A	

CONSENT/RISK/BENEFIT RATIO

Problem/AE listed in Consent/Assent Form: ○ Yes ○ No ○ No Consent Form

Consent/Assent should be revised:	○ Yes ○ No	If yes, attach revised form with changes highlighted. ○ No Consent Form

Presently enrolled subjects should be informed of Problem/AE: ○ Yes ○ No

If yes, describe your plan for informing subjects:

If the Risk/Benefit Ratio has changed in light of Problem/AE, describe the change:

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Shaded Area to be completed for IBC Protocols Only

Relationship of Event to study gene transfer product ___ Unrelated ___ Unlikely ___ Possible ___ Probable ___ Definite

Reports submitted to (check all that apply):
- ☐ NIH Office of Biotech Activities: Submit if research involves gene transfer
- ☐ Sponsor (print or e-mail)
- ☐ FDA: Submit if research is FDA regulated

SUBJECT DEMOGRAPHICS

Research Participant's date of death ___/___/___ or ☐ N/A

Research Participant's weight in kgs ____ kgs or ☐ N/A

Research Participant's height in cms ____ cms or ☐ N/A

What Arm/Cohort/Treatment group was the subject assigned to? _____ or ☐ N/A

Was subject dosed with the gene transfer product? ___ Yes ___ No ___ Information Not Available ___ N/A

PRODUCT AND DOSING INFORMATION

Name of gene transfer product:

Vector type (e.g. adenovirus)

Vector sub-type (e.g. type 5, also include relevant deletions)

Lot number

Was the agent manufactured at a National Gene Vector Laboratory (NGVL)?

Route of administration

Site of administration

Did subject receive the dose specified in the protocol? ___ Yes ___ No
If not, what dose was given?

Date of first exposure to study agent? ___/___/___ Date of most recent exposure to study agent? ___/___/___.

Total dose received prior to this event?

Total dose quantity administered to subject to date:

Unit of measure for a single dose Dose quantity in a single administration

If courses of gene transfer agent used, how many courses were given prior to this event?

How many doses on the last course were given?

Was the administration of this product stopped because of this adverse event? ___ Yes ___ No

Name of other treatment (s) (medications, radiation, surgery)
received by research participant as required by the protocol:

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For Clinical Studies where the Principal Investigator (PI) is not a physician:

If this report is for a clinical study and the Principal Investigator (PI) is not a physician, a sub-investigator who is licensed to recognize, diagnose, and treat adverse events (e.g., MD or DMD) must review this report, and you, the PI, must confirm that an MD/DMD sub-investigator has reviewed and acknowledges the contents of this report:

Confirmed? ◯ Yes ◯ No

Principal Investigator Signature: _____ Date _____