Template for Reporting Adverse Events In Human Gene Transfer Trials

This template is intended to facilitate the reporting of adverse events in human gene transfer trials. You may download this as a Word document and the fields will expand according to the amount of text entered. Use of this template is not required and other formats (e.g. AdEERS reports, MedWatch forms) may be acceptable provided that they include all the information specified in M-I-C-4-a of the *NIH Guidelines for Research Involving Recombinant DNA Molecules.* (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html)

Submitting this completed template to the NIH Office of Biotechnology Activities alone does NOT fulfill the reporting requirements of other agencies. However, some agencies may accept submission of a duplicate copy of this completed template. You should verify with the other parties to whom you report whether the use of this template is acceptable.

Completed reports may be sent via U.S. mail, courier service, e-mail, or facsimile to:

NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
(For all non-USPS deliveries use Zip Code 20817)
Telephone 301-496-9838
Fax 301-496-9839
E-mail address for Reporting Adverse Events: GeMCRIS@od.nih.gov
General E-mail: oba@od.nih.gov
Website: www4.od.nih.gov/oba/

PROTOCOL AND EVENT TYPE	
NIH/OBA (RAC) Protocol Number	
FDA IND number	
Date this report completed:	
Seriousness of the AE (choose one)	Death Life-threatening Initial or prolonged hospitalization Disability Congenital anomaly Required intervention to prevent permanent impairment/damage Other medically important condition Non-serious
Severity of Event	Minimal Moderate Severe Life- Threatening Fatal
Was this event expected in terms of its severity?	Yes No
Was this event expected in terms of its specificity?	Yes No
Relationship of Event to gene transfer product	Unrelated Unlikely Possible Probable Definite
Attribution of AE Attribution of AE, continued	Concomitant medication Product Intervention Underlying disease Route of administration Other suspected cause (describe)
Type of report	Initial Follow-up
DEMOGRAPHICS	
PI Name	
Name of Clinical Trial Site/Organization	
PI Telephone Number	
PI E-mail Address	
Reporter name	
Reporter Telephone number	

Reporter E-mail address	
Research Participant's study identification number	
Research Participant's gender	
Research Participant's date of birth	
Research Participant's date of death	
Research Participant's weight in kgs	
Research Participant's height in cms	
Which Arm/Cohort/treatment group was the subject assigned to?	
Was subject dosed?	Yes No Information Not Available
What study agent was received:	IND agent Placebo Blinded Study Agent
Were there any Protocol Deviations/Violations/Exceptions for this participant?	Yes:_____ _____ _____ No
DETAILED ADVERSE EVENT INFORMATION	
Adverse Event Date	
Description of Event	
Relevant tests (e.g. x-rays) and results	
Treatment (s) of Adverse Event (Include medications used to treat this event.)	
Name of Concomitant Medications (Do not include medications used to treat this event.)	
Pre-existing conditions/ relevant clinical history (if this is an oncology trial, please designate primary disease, e.g. ovarian cancer)	
Date(s) of treatment(s) of the adverse event	

Was autopsy performed?	Yes No
Date of autopsy	_____ or Not Applicable _____
Outcome of the event	Recovered/resolved Recovering/resolving Not recovered/not resolved Recovered/resolved with sequelae Fatal Unknown
Documentation accompanying the report (e.g., H& P, Progress Notes, Discharge Summary, Lab or Autopsy Reports, Other, etc.)	
Description of any "other" documentation	
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 an NGVL?	
Route of administration	
Site of administration	
Did subject receive the dose specified in the protocol?	
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 used, how many 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?	
Name of other treatment (s) (medications, radiation, surgery) received by research participant as required by the protocol	