Unanticipated Problem (UP)/ Serious Adverse Event (SAE) Report Form

For this form, a serious adverse event is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/incapacity, results in congenital anomalies/birth defects, or by the opinion of the investigators represents other significant hazards or potentially serious harm to research subjects or others. A serious adverse event is considered unexpected if it is not described in the Package Insert or the Investigator's Brochure (for FDA investigational agents), in the protocol, or the informed consent document.

INSTRUCTIONS:
Please complete the information requested below and forward one copy to the IRB as soon as possible, but not later than seven (7) days in the case of death or life-threatening serious adverse events or within fifteen (15) days after the occurrence of all other forms of serious adverse events. The IRB office will immediately forward a copy to the Clinical Director. Also, continue to follow the FDA and the NIH Office reporting requirements if your research involves an IND/IDE or gene transfer.

PROTOCOL #:	***PROTOCOL TITLE:***
PRINCIPAL INVESTIGATOR:	Department: Office Phone: Fax: E-mail:
DATE OF SERIOUS ADVERSE EVENT:	____/____/_____
LOCATION OF SAE *(e.g., at CCC or elsewhere):*	
WAS THIS AN UNEXPECTED ADVERSE EVENT?	Yes ☐ No ☐
WAS THIS A SERIOUS ADVERSE EVENT?	Yes ☐ No ☐
BRIEF DESCRIPTION OF SUBJECT(S) *(Do NOT include identifiers.)*	*SEX:* ☐M/ ☐F *AGE*: _____ Diagnosis:
BRIEF DESCRIPTION OF THE NATURE OF THE SERIOUS ADVERSE EVENT:	

CATEGORY (outcome) OF THE SERIOUS ADVERSE EVENT:	***RELATIONSHIP OF SERIOUS ADVERSE EVENT TO RESEARCH:***
☐ death ☐ disability/incapacity ☐ life-threatening ☐ congenital anomaly/birth defect ☐ hospitalization-initial or prolonged ☐ required intervention to prevent permanent impairment ☐ other	☐ 1 = unrelated (clearly not related to the research) ☐ 2 = unlikely (doubtfully related to the research) ☐ 3 = possible (may be related to the research) ☐ 4 = probable (likely related to the research) ☐ 5 = definite (clearly related to the research)
HAVE SIMILAR ADVERSE EVENTS OCCURRED ON THIS PROTOCOL?	Yes ☐ No ☐ If "Yes," how many? Please Describe:

What steps do you plan to take as a result of the adverse event reported above? Provide documentation to the IRB for review and approval of any of the steps checked below.	☐ No action required ☐ Revise protocol to eliminate apparent immediate hazards to subjects ☐ Modification of inclusion or exclusion criteria to mitigate newly identified risks ☐ Implementation of additional procedures for monitoring subjects ☐ Suspension of enrollment of new subjects ☐ Notify currently enrolled subjects ☐ Suspension of research procedures in currently enrolled subjects ☐ Modification of consent documents to include a description of newly recognized risks (site and study-wide) ☐ Provision of additional information about newly recognized risks to previously enrolled subjects ☐ Terminate or suspend protocol ☐ Other: _____

Staff member completed this form (print):	***Signature***	***DATE:***
Principal Investigator's name (print)	***PI Signature***	***DATE:***