

ADVERSE EVENT / UNANTICIPATED PROBLEM REPORT

Protocol #:	SAE / AE: #
Principal Investigator:	Name of the person completing the form:
Please select: [To select, press double click on the box] <input type="checkbox"/> Unanticipated Problem (UP) <input type="checkbox"/> Adverse Event (AE) <input type="checkbox"/> Serious Adverse Event (SAE)	ID of Participant: _____
	Type of Report: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-Up # _____ <input type="checkbox"/> Final
CHRONOLOGY	
1. Date UP/AE/SAE occurred: _____ (mm/dd/yyyy)	2. Date PI or staff informed of/made aware of UP/AE/SAE: _____ (mm/dd/yyyy)
3. Date UP/AE/SAE reported to the Sponsor: _____ (mm/dd/yyyy) <input type="checkbox"/> <i>If Protocol is not sponsored mark here</i>	4. Date UP/AE/SAE reported to the IRB: _____ (mm/dd/yyyy)
Was this UP/AE/SAE reported within the required reporting time period? <input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>In order to ensure prompt reporting to the IRB of unanticipated problems or adverse events involving risks to participants or others, regulatory agencies, and institutional officials, the IRB requires timely report of the following events:</p> <ul style="list-style-type: none"> - Unanticipated problems that are serious adverse events should be reported to the IRB within 1 week of the investigator becoming aware of the event. In the case of internal (MSC or affiliated institutions) fatal or life-threatening events, these must be reported within 48 hrs. - Any other internal unanticipated problems should be reported to the IRB within 2 weeks of the investigator becoming aware of the problem. - IRB must report unanticipated problems involving risks to participants to appropriate institutional officials, the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator. 	
Brief Description of the UP/AE/SAE:	

<p>Severity/grade of SAE reported:</p> <ul style="list-style-type: none"><input type="checkbox"/> death<input type="checkbox"/> disability/incapacity<input type="checkbox"/> life-threatening<input type="checkbox"/> congenital anomaly/birth defect<input type="checkbox"/> hospitalization-initial or prolonged<input type="checkbox"/> required intervention to prevent permanent impairment<input type="checkbox"/> other, specify:	<p>Attribution of SAE reported by the PI:</p> <ul style="list-style-type: none"><input type="checkbox"/> 1 = unrelated (clearly not related to the research)<input type="checkbox"/> 2 = unlikely (doubtfully related to the research)<input type="checkbox"/> 3 = possible (may be related to the research)<input type="checkbox"/> 4 = probable (likely related to the research)<input type="checkbox"/> 5 = definite (clearly related to the research)
Protocol/Consent revision and Participant Notification of the UP/AE/SAE	
<p>Are any protocol and/or consent form changes being proposed as a result of this unanticipated problem/adverse event report?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No action required</p> <p>If Yes, select ALL that apply:</p> <ul style="list-style-type: none"><input type="checkbox"/> amend consent document<input type="checkbox"/> amend protocol<input type="checkbox"/> inform current subjects<input type="checkbox"/> terminate or suspend protocol<input type="checkbox"/> other, describe:	<p>Will currently enrolled participants be notified of this adverse event?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If Yes, please explain:</p>