



**Institutional Review Board**  
**Louisiana State University**  
**131 David Boyd Hall, Baton Rouge, LA 70803**  
[irb@lsu.edu](mailto:irb@lsu.edu)

**Unanticipated Problems Involving Risks to Subjects  
or Others / Adverse Event Report Form**

TO BE COMPLETED BY PRINCIPAL INVESTIGATOR IF PI IS A STUDENT, ALL CORRESPONDENCE SHOULD BE COPIED TO THE STUDENT'S RESEARCH ADVISOR		IRB #	
PI NAME AND CONTACT INFORMATION:			
NUMBER OF PARTICIPANTS AFFECTED:			
<input type="checkbox"/> INITIAL REPORT <input type="checkbox"/> FOLLOW-UP REPORT		EVENT OCCURRED AT: <input type="checkbox"/> LSU OR AFFILIATED SITE <input type="checkbox"/> NON-ASSOCIATED SITE	
EVENT ONSET:        /        /		EVENT TERMINATION:        /        /	
EVENT CONTINUING? <input type="checkbox"/> YES <input type="checkbox"/> NO			
DESCRIPTION OF PROBLEM OR EVENT:		NUMBER OF SUBJECTS EXPERIENCING THE SEVERITY: <input type="checkbox"/> MILD <input type="checkbox"/> MODERATE <input type="checkbox"/> SEVERE <input type="checkbox"/> SERIOUS <input type="checkbox"/> LIFE-THREATENING <input type="checkbox"/> DEATH	
ACTION TAKEN AND RESULT:			
EVENT RELATED TO RESEARCH? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNDETERMINED		CAUSE OF EVENT (if not related to research):  <input type="checkbox"/> UNDETERMINED	
HAS SAME EVENT OCCURRED PREVIOUSLY? <input type="checkbox"/> YES <input type="checkbox"/> NO		IF YES, HOW OFTEN?	
SHOULD CONSENT FORM BE REVISED TO INFORM SUBJECTS OF EVENT? <input type="checkbox"/> YES ~ attach revised consent form with the changes highlighted <input type="checkbox"/> NO ~ EXPLAIN:			
SHOULD ENROLLED SUBJECTS BE INFORMED OF EVENT? <input type="checkbox"/> YES <input type="checkbox"/> NO		HAVE THEY BEEN INFORMED? <input type="checkbox"/> YES <input type="checkbox"/> NO	

**Submit a completed copy of this form to [irb@lsu.edu](mailto:irb@lsu.edu).**  
**If changes to the consent form are required, send the new form also.**

OFFICE USE ONLY:

☐ Adverse Event

☐ Serious

☐ Non-serious

☐ UPIRTSO

Action Taken: