TEXAS Health and Human Services

IRB2 ADVERSE EVENT & UNANTICIPATED PROBLEM REPORT

Instructions:

Complete and submit this report to the IRB2 Administrator immediately. If there is new information provided in this report that may include new and/or increased risks to future participants, a study amendment must be submitted to revise the approved protocol and possibly, the approved informed consent document.

Principal Investigator:	
IRB2 Tracking Number:	Date of Event:
1. Describe *in detail* the nature and timing of the event.	
2. Describe what research procedures were involved at the time of the event.	

3. Did the event *involve harm* to one or more subjects or others, or place subjects or others at increased risk of harm?
Check one: ◯ Yes ◯ No
4. Describe the treatment offered to research participants if injury was involved. If no injury was involved, indicate "NA."
5. Did the event *occur beyond the expected frequency and specificity* of similar actions outlined in the research protocol?
Check one: ◯ Yes ◯ No
6. Did the event directly relate to the research procedure(s)?
Check one: ◯ Yes ◯ No
If your computer allows email submission, after completing the form click the "Submit" button located below, otherwise submit the form and applicable documentation.
Submit