ADVERSE EVENT & UNANTICIPATED PROBLEM REPORT

IRB2

Instructions:

*Complete and submit this report to the IRB2 coordinator 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:

Protocol #:

Date of Event:

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| 1. Describe *in detail* the nature and timing of the event. |
| 1. Describe what research procedures were involved at the time of the event. |
| 1. 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 |
| 1. Describe the treatment offered to research participants if injury was involved. If no injury was involved, indicate “NA.” |
| 1. Did the event *occur beyond the expected frequency and specificity* of similar actions outlined in the research protocol? Check one: Yes No |
| 1. Did the event directly relate to the research procedure(s)? Check one: Yes No |