University of Puerto Rico • Medical Sciences Campus
Human Research Protection Office

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] ☐ Unanticipated Problem (UP) ☐ Adverse Event (AE) ☐ Serious Adverse Event (SAE)	**ID of Participant:** _____ **Type of Report:** ☐ Initial ☐ Follow-Up #____ ☐ 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) ☐ ***If Protocol is not sponsored mark here***	**4. Date UP/AE/SAE reported to the IRB:** _____ (mm/dd/yyyy)

Was this UP/AE/SAE reported within the required reporting time period? ☐ **Yes** ☐ **No**

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:

- **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:

Severity/grade of SAE reported:	**Attribution of SAE reported by the PI:**
☐ death ☐ disability/incapacity ☐ life-threatening ☐ congenital anomaly/birth defect ☐ hospitalization-initial or prolonged ☐ required intervention to prevent permanent impairment ☐ other, specify:	☐ 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)
Protocol/Consent revision and Participant Notification of the UP/AE/SAE	
Are any protocol and/or consent form changes being proposed as a result of this unanticipated problem/adverse event report? ☐ **Yes** ☐ **No action required** If Yes, select ALL that apply: ☐ amend consent document ☐ amend protocol ☐ inform current subjects ☐ terminate or suspend protocol ☐ other, describe:	Will currently enrolled participants be notified of this adverse event? ☐ **Yes** ☐ **No** ☐ **N/A** If Yes, please explain: