**Headquarters, US Army Medical Research and Materiel Command Institutional Review Board**

**Research Monitor Report for**

**Serious Adverse Events (SAEs), Unanticipated Adverse Device Effects (UADEs), and Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs)**

Use this form for the Research Monitor’s report of unexpected related SAEs, all UADEs, and UPIRTSOs requiring **prompt** reporting to the Headquarters, US Army Medical Research and Materiel Command Institutional Review Board (HQ USAMRMC IRB).

Place the cursor in the cell and type. The cell will expand to accommodate all text. Tab to next field.

**Date of this Report:**       **Date of Initial Report:**       **Subject ID #:**

1. **Study Information**

HQ USAMRMC IRB Log #:       Institutional Protocol #:

Protocol Title:

Principal Investigator:

Date/Time you learned of the event:      

1. **Event Assessment**

Provide your analysis of the following:

* Seriousness of the event
* Relatedness of the event to the research procedures or interventions
* Harms caused or increased risk of harm to subjects or others
* The event’s effect on research activities and the integrity of the data
* Whether or not the event was anticipated
* The outcome(s) of the event
* The proposed corrective action / preventive action plan

1. **Describe your concurrence with the details of the initial event report provided by the Principal Investigator or provide the details of the event as you understand them.**

**By signing, I attest that the report is complete and accurate:**

**Research Monitor’s Name Signature Date**