Use this form for the initial and follow-up reporting of events requiring prompt reporting (SAEs that are unexpected and related to research, UPIRTSOs, UADEs, and Major Deviations). Also use this form to notify the HQ USAMRDC IRB of any change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to the research subject(s). A glossary with useful terms to assist in answering the questions is provided in the back of this form.

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

**Date of this Report:**

1. **Study Information.**

HQ USAMRDC IRB Log #:       Institutional Protocol #:

Protocol Title:

Principal Investigator:

Alternate Point of Contact for this Reportable Event:

**B. Event Description.**

 1. Date of the Event:

 2. Date of Discovery:

 3. Is this an initial report or a follow-up report?

 4. Number of Subjects Affected:

 5. Description of the Event:

|  |  |
| --- | --- |
|  6. Provide a description of the initial actions taken by the research team to manage the event. Specify whether enrollment of new subjects or any other research procedures have been suspended while the event is under review. If applicable, state whether the subject(s) impacted by or involved in the event have been removed from the study or otherwise have been taken off of the experimental intervention as part of the actions taken to mitigate the event.       |   |

 7. Has the Research Monitor written a report related to the event?

**C. Reportable Event Assessment. *Choose the appropriate event and answer the questions in that section. A UPIRTSO assessment must be filled out for all reportable events.***

 **1. Major Deviation Assessment:**

1. Does the deviation potentially adversely affect the subject’s or subjects’ rights, safety, welfare, or willingness to participate?

[ ]  No [ ]  Yes

1. Does the deviation affect the design of the study and/or the integrity of the data?

[ ]  No [ ]  Yes

1. Does the deviation make a substantial alteration to risks to subjects?

[ ]  No [ ]  Yes Explain:

 d. Was this deviation made to eliminate an apparent immediate hazard to the research subject(s) or in response to an emergency or life-threatening situation?

 [ ]  No [ ]  Yes Explain:

e. Is this deviation one in a series of repeated similar deviations?

 [ ]  No [ ]  Yes

 \*If you answered “NO” to all of the above, the event is not a Major Deviation.

 **2. Serious Adverse Event Assessment.**

 a. Was the adverse event life-threatening, or has it resulted in death?

 [ ]  No [ ]  Yes Explain:

 b. Did the adverse event result in inpatient hospitalization or prolongation of existing hospitalization?

 [ ]  No [ ]  Yes Explain:

 c. Did the adverse event result in persistent disability or incapacity or in a congenital anomaly or birth defect?

 [ ]  No [ ]  Yes Explain:

 d. Based on medical judgment, could the adverse event have jeopardized subjects’ health?

 [ ]  No [ ]  Yes Explain:

 e. Did the adverse event require medical or surgical intervention?

 [ ]  No [ ]  Yes Explain:

 f. Was the adverse event unexpected?

 [ ]  No [ ]  Yes

 g. Was the adverse event possibly or definitely related to study participation?

 [ ]  No [ ]  Yes

 h. Was the event associated with or caused by a device?\*

 [ ]  No [ ]  Yes Explain:

  ***\* If the answer is yes, the event could be an unanticipated adverse device effect; the PI must contact the Sponsor for reporting to the FDA. Prompt reporting is required to the IRB.***

 **3. UPIRTSO Assessment.\***

a. Was the event unexpected given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the population being studied?

[ ]  No [ ]  Yes Explain:

 b. Was the event related or possibly related to a subject’s participation in the research?

 [ ]  No [ ]  Yes Explain:

c. Does the event suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social) than was previously known or recognized?

 [ ]  No [ ]  Yes Explain:

***\*If you answered “YES” to all of the above, the event is a UPIRTSO.***

1. **Corrective and Preventive Actions.**

What actions have been taken thus far in response to this reportable event?

Does the consent form require revision based on the reportable event?

[ ]  No [ ]  N/A [ ]  Yes. \*Briefly describe the proposed changes:

Does the protocol require revision based on the reportable event?

[ ]  No [ ]  Yes. \*Briefly describe the proposed changes:

Do past/currently enrolled participants require notification of this reportable event or require re-consent?

[ ]  No [ ]  Yes. \*Briefly describe the proposed plan for notification and/or re-consenting subjects:

What other actions, if any, will be implemented in response to this event to prevent future, similar occurrences or to follow-up?

**\**Note: if applicable, an amendment request and the revised consent form / protocol / letter to subjects, etc. must be submitted separately from this report.***

**By signing below,** **I attest to this report’s completeness and accuracy.**

**Principal Investigator’s Name Signature**  **Date**

**GLOSSARY**

**Major Deviation:** Unapproved change in previously approved research activities, implemented without IRB approval, which may potentially adversely affect subjects’ rights, safety, welfare or willingness to continue participation, or may affect the scientific design of the study and/or the integrity of the study or its resultant data.

**Serious Adverse Events:** Those events that result in death, are life-threatening, result in inpatient hospitalization or prolongation of existing hospitalization, result in persistent disability or incapacity, result in congenital anomaly or birth defect; or, based on medical judgment, may jeopardize subjects’ health and may require medical or surgical intervention.

**Unanticipated Problem Involving Risk to Self or Others (UPIRTSO)**: Any incident, experience, or outcome that meets all of the following criteria: unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; related or possibly related to a subject’s participation in the research; and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

**Unanticipated Adverse Device Effect**: An unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.3(s)).

**Related:** An event is considered “related to the research procedures” if the cause of the event is deemed probably or definitely related to the investigational product or a procedure that was performed for the purposes of the research. NOTE: Possibly related events do not require expedited reporting UNLESS the event suggests that the research places subjects at greater risk than was previously known or recognized (i.e., changes to the study conduct and/or documents are required to mitigate risk and/or participants’ willingness to participate may be adversely impacted). If the event suggests that the research places subjects at greater risk than was previously known or recognized, the event may be an unanticipated problem involving risks to subjects or others and requires assessment by the IRB.

**Unexpected:** An event is unexpected if:

• It is not reflected in the protocol-related documents (such as the IRB-approved research protocol, the investigator’s brochure/package insert, the device investigational plan, or the current IRB–approved informed consent document).

• It is not accurately reflected in protocol related documents. In essence, an event would be unexpected if it is at a frequency or severity that has not previously been observed and described in the protocol-related documents.

• It is mentioned in the investigator’s brochure/package insert as occurring within a class of drugs or devices, or as anticipated based on the pharmacological properties or design of the product, but, are not mentioned as being observed with the particular product under investigation.