Date:
WRAIR #:
PI/POC:
HSPB POC:
Deviation/UAP/SAE/SUSAR/UADE #:

To Be Filled by HSPB POC

Brief Description of the event:

Brief requirement of the IRB (how would you like the Board to review, what do they need to look at):

Additional Relevant Information (Include the following information: 1) potential impact to subjects and any mitigating factors; 2) historically how have things of this nature been processed; 3) are there any precedents being made as a result of this review; 4) are there previous/concurrent IRB actions related to this issue? :

To Be Filled By IRB Reviewer

Choose one of the two following categories depending on the type of study:

- ☐ **SAEs/SUSARs/UADEs from a clinical trial (referred from UWS-HP-619) that are both related to study participation and unanticipated in nature. Complete item #2 for determination as a UPIRTSO.**

- ☐ **AEs that are Unanticipated from non-product studies or UAPs that are potential UPIRTSOs. Complete items #1 and 2 below:**

1. **Determination as an Adverse Event:**

   Did any participant experience:

Untoward/unfavorable medical occurrence?	☐ YES	☐ NO
Abnormal signs or symptoms?	☐ YES	☐ NO
Disease?	☐ YES	☐ NO

If 'Yes' to any of the above, this is an adverse event: continue below to determine whether the adverse event was SERIOUS. If 'No' to all of the above, please continue to 'Determining UPIRTSOs' (number 2 below)

Did the adverse event:

Result in Death or places the subject at immediate risk of death?	☐ YES	☐ NO
Required inpatient hospitalization or prolonged hospitalization?	☐ YES	☐ NO
Result in persistent or signification disability or incapacity?	☐ YES	☐ NO
Result in congenial anomaly or birth defect?	☐ YES	☐ NO
May jeopardize the subject's health?	☐ YES	☐ NO
Require medical/surgical intervention to prevent any of the outcomes listed immediately above?	☐ YES	☐ NO

If 'Yes' to any of the above, this Adverse Event is <u>SERIOUS</u>. Please determine whether the event was related to study participation.

Is the AE Related to study participation or to any study products? ☐ YES ☐ NO

If yes, then the AE is considered related to the study product or study participation.

Please determine whether the event was anticipated below.

Is the nature, severity, or frequency of the adverse event, occurring in one or more subjects participating in the research, consistent with either:

The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or	☐ YES	☐ NO
The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.	☐ YES	☐ NO

If either of the statements above are 'No", this Adverse Event was <u>UNANTICIPATED.</u> If the adverse event was determined to be Serious, Related, and Unanticipated, then it should be considered as a potential UPIRTSO as per #2.

Notes/discussion points:

2. Determining Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO)

Was the event/action:

Unexpected In terms of nature, severity or frequency given the protocol procedures and the subject population?	☐ YES	☐ NO
Related or possibly related to a subject's participation in the Research? (Reasonable possibility that the incident, experience or outcome may be been caused by research participation)	☐ YES	☐ NO
Suggests the research places subjects or others at a greater risk of harm (physically, psychological, economic or social) than previously known or recognized?	☐ YES	☐ NO

In order to be considered a UPIRTSO, all three of these must be 'Yes'.

Notes/discussion points:

Complete for potential Major Deviations:

1. Determining Deviations:

Was a change in the protocol conduct implemented without WRAIR IRB approval and authorization by WRAIR Commander? This change may be intentional or unintentional and may stem from actions by any participant in the study, including investigators, subjects or other individuals.

☐ YES ☐ NO

If 'Yes', this is considered a deviation. Please determine if the deviation is considered to be a major or minor deviation.
Did the deviation have the potential to:

Affect rights or welfare of the participants/subjects?	☐ YES	☐ NO
Increase risks of participants or others?	☐ YES	☐ NO
Change subjects' willingness to continue participation?	☐ YES	☐ NO
Compromises the integrity of the study in a way that study objectives cannot be met?	☐ YES	☐ NO

If 'Yes' to any of the above, this is a <u>MAJOR DEVIATION.</u> If determined to be a major deviation, then determine if the major deviation resulted in serious and/or continuing non-compliance in item #2 below.

Notes/discussion points:

2. <u>Non-Compliance:</u>

- ☐ *Continuing Non-compliance:* A pattern of non-compliance that suggests a likelihood that, without intervention, instances of non-compliance will recur, or that indicates an unwillingness to comply with or a lack of knowledge of Federal and DoD regulations, policy, and law, determinations or requirement of the IRB and/or Headquarters, USAMRDC (HQ USAMRDC) or the research protocol.

- ☐ *Serious Non-compliance*: Non-compliance that could adversely affect the rights, safety or welfare of participants; place participants at increased risk of harm; cause harm to participants; affect subjects' willingness to participate in research; or damage or compromise the scientific integrity of research data.

If determined to be Serious and/or Continuing Non-compliance, then the major deviation should be reported as outlined in SOP UWS-HP 606, Non-compliance Procedures.

Notes/discussion points:

3. <u>DECISION:</u>

The WRAIR IRB determined this/these event(s) to be:

- ☐ Adverse Event(s) not Product Related
  - Unanticipated, Related, and Serious (UPIRTSO)
  - Not Reportable as an UPIRTSO

- ☐ SAEs/SUSARs/UADE from Clinical Trials
  - Unanticipated, Related, and Serious (UPIRTSO)
  - Not Reportable as an UPIRTSO

- ☐ Unanticipated Problem
  - Reportable as an UPIRTSO
  - Not Reportable as an UPIRTSO

- ☐ Deviation
  - Major
  - Minor (if minor deviation, then there is no serious or continuing non-compliance)

- ☐ Non-Compliance
  - Serious
  - Continuing

Requiring the following corrective action (as applicable):

_____ _____

IRB Reviewer Signature Date