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| **Walter Reed Army Institute of Research**  **Human Subjects Protection Branch**  **Protocol Deviation/Unanticipated Problem Report Form** |

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**Date Reported:**

**WRAIR Protocol#:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Deviation/Unanticipated Problem #:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator:**

**WRAIR Point of Contact:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Study Title:**

**1. Describe the deviation(s) or unanticipated problem(s) (to include a description of the event, the date of event, date of discovery, the number of occurrences, number of subjects affected, etc.) :**

*(Or Attach)*

**2. Who is the Sponsor of the Study? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**3. Has the Sponsor been notified of the deviation(s) or unanticipated problem?**

**YES NO NA**

**3. Has the Sponsor agreed to allow the participant(s) to continue? YES NO NA**

**4. In your judgment, has the deviation(s) or unanticipated problem(s) affected the rights or welfare of the participant? If yes, please describe. YES NO**

**5. In your judgment, has the deviation(s) or unanticipated problem(s) increased the risk to the participant? If yes, please describe. YES NO**

**6. Describe any follow-up action taken to prevent this/these deviation(s) or unanticipated problem(s) from occurring in the future.**

1. **Does this protocol deviation or unanticipated problem require revision of the protocol and/or consent form?**

**[ ] Yes** *(if yes, please submit an Amendment and revised documents with changes marked)*

**[ ] No**

**Signed : Date: \_\_\_\_\_\_\_\_\_\_\_\_**

**(Principal Investigator and/or WRAIR POC)**

*If the deviation or unanticipated problem involves more than one study volunteer, signature signifies the responses on this form encompass all the deviations or unanticipated problems. Use separate forms when appropriate.*