



Walter Reed Army Institute of Research
Standard Operating Procedure



Appendix A: HSPB Protocol Deviation/Unanticipated Problem Report Form	SOP No. UWS-HP-621
	Version .03
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Walter Reed Army Institute of Research Human Subjects Protection Branch Protocol Deviation/Unanticipated Problem Report Form

e-mail to: usarmy.detrick.medcom-wrair.mbx.hspb@health.mil

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



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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.

7. 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.