



**Walter Reed Army Institute of Research  
Standard Operating Procedure**



Appendix B: <b>HSPB Protocol Deviation/Unanticipated Problem Action Sheet</b>	SOP No. <b>UWS-HP-621</b>
	Version <b>.03</b>
Effective Date 3 March 2023	Page <b>1 of 2</b>

**HSPB Protocol Deviation/Unanticipated Problem Report Action Sheet**

**WRAIR Protocol #:** \_\_\_\_\_ **HSPB POC:** \_\_\_\_\_

**PI/WRAIR POC:** \_\_\_\_\_ **Sponsor:** \_\_\_\_\_

**Date Submitted for Review:** \_\_\_\_\_ **Date of Report:** \_\_\_\_\_

**Date of event:** \_\_\_\_\_

**Reviewing IRB (Check one):**

- WRAIR IRB (WRAIR IRB Chair/Designee)
- Reliance on: \_\_\_\_\_ (WRAIR IRB Administrator/Designee)

**HSPB Office (Check one)**

- Review as Potential Major Deviation
- Review as Potential UPIRTSO

**Documents Provided (Check all that apply):**

- Initial Deviation/Unanticipated Problem Report
- Follow-up Deviation/Unanticipated Problem Report
- Report from Other IRB/ERCs
- Other (e.g., Continuing Review Report): \_\_\_\_\_

**For studies reviewed by the WRAIR IRB, IRB Chair/Designee (Complete Action Taken, Reporting, as applicable, and Sign and Date the Form to show that the report has been reviewed)**

**Action Taken (Check one):**

- Request for More Information: \_\_\_\_\_



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- Accept with no further action required (not a major deviation or potential UPIRTSO)
- Accepted; requires modification to protocol-related documents
- Major Deviation, Refer to Full WRAIR IRB for Suspected Protocol Non-compliance (Serious and/or Continuing, refer to SOP UWS-HP-606).
- Refer to Full WRAIR IRB for review and determination as a possible UPIRTSO.
- Accept the deviation or UAP (not a major deviation or potential UPIRTSO) and refer to Full WRAIR IRB for information only. Reason: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

**For studies where the WRAIR relies on another institution for IRB review, IRB Administrator (Complete Action Taken, Reporting, as applicable, and Sign and Date the Form to show that the report has been reviewed)**

**Action Taken (Check one):**

- Request for More Information: \_\_\_\_\_
- Information Only Acknowledgement with no further action (not a major deviation or a potential UPIRTSO)
- Acknowledge the deviation as serious and/or continuing noncompliance as determined by the reviewing IRB, and report to the USAMRDC OHARO OHRO and/or the relevant federal department or agency head on behalf of the WRAIR IO.
- Acknowledge the UPIRTSO as determined by the reviewing IRB, and report to the USAMRDC OHARO OHRO and/or the relevant federal department or agency head on behalf of the WRAIR IO.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_