



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



Appendix C: HSPB Protocol Deviation/Unanticipated Problem Log	SOP No. UWS-HP-621
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Human Subjects Protection Branch Protocol Deviation/Unanticipated Problem Log

Instructions: Complete this form documenting all protocol deviations, to include major deviations and unanticipated problems (to include UPIRTSOs) that occur in a study and forward to the Human Subjects Protection Branch (HSPB) at the time of continuing review or end of study, whichever comes first.

DEVIATION - A change in the conduct of a protocol, intentional or unintentional, implemented without approval from the WRAIR IRB and implementation approval from the WRAIR Commander. The deviation may stem from actions by any participant in the study, including investigators, subjects, or other individuals. A deviation may or may not result in circumstances posing an increase in the physical, psychological, economic, legal, and/or other risks incurred during the conduct of a protocol.

MAJOR DEVIATION - A major deviation is non-adherence to the IRB-approved protocol that has the potential to affect the rights and welfare of the research participant, to increase the risk to the research participant, to change the willingness of the volunteer to continue participation, or to compromise the integrity of the study data in such a way that the study objectives may not be achieved.

UNANTICIPATED PROBLEM - Unanticipated problems include any unforeseen or unexpected incident or experience (including an unanticipated adverse event) that occurs during the conduct of the research and that was not described in the information reviewed by the IRB (i.e. research protocol or informed consent document). Unanticipated problems can include subject complaints or protocol violations. Other examples include, but are not limited to: exposure to HIV or other infectious disease due to an unintentional needle stick, disclosure of protected health information, occurrences of breach of confidentiality, destruction of study records, unaccounted for study drug, etc.

UPIRTSOs - Unanticipated Problems Involving Risks to Subjects or Others, include any incident, experience, or outcome, that meets all of the following criteria: (1) 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; (2) related or possibly related to participation in the research (meaning that there is reasonable possibility that the incident, experience or outcome may have been caused by the procedures involved in the research); and (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

****Please note: This is not the Protocol Deviation/Unanticipated Problem Report to be used for initial notification of major deviations or unanticipated problems! All major deviations and UPIRTSOs must be reported to the HSPB within 48 hours upon becoming aware of the deviation and a Protocol Deviation Report must be submitted within 10 working days from knowledge of the event.***



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Study Name:	Principal Investigator:
WRAIR Protocol Number:	PI or Study Coordinator Contact info:

Subject

ID#	Major		Deviation?	Deviation?	UAP?	UPIRTSO?	Description of Event
	DATE	Deviation?					

I acknowledge the above-listed protocol deviations/unanticipated problems for this study.

Principal Investigator Signature

Date