



**Walter Reed Army Institute of Research
Division of Human Subjects Protection
Standard Operating Procedure**

SOP Title:	Deviation and Unanticipated Problem Reporting	SOP No.	UWZ-C-621
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Signatures and Dates:

For signatures, please see the original at the office of the Human Subjects Protection Branch

Review/Approval for unchanged documents

Date	Author	QA Review	Approving Authority



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1. Purpose/Scope

This Standard Operating Procedure (SOP) outlines the process for documentation and review of deviations and unanticipated problems. This SOP applies to Walter Reed Army Institute of Research (WRAIR) Division of Human Subjects Protection (DHSP) staff, the WRAIR Institutional Review Board (IRB) chair or designee, the WRAIR IRB members, and the WRAIR Institutional Official (IO).

2. Responsibilities

a. WRAIR DHSP staff are responsible for:

- 1) Receiving telephone, email, facsimile, and written reports for both deviations and unanticipated problems.
- 2) Triaging the deviations and/or unanticipated problems, requesting additional information as necessary, and submitting to the WRAIR IRB Chair and/or WRAIR IRB, as appropriate, for review.
- 3) Sending the WRAIR IRB communications to the PI regarding the review of the deviations and unanticipated problems.
- 4) Archiving all deviation and unanticipated problem reports in the protocol regulatory file.
- 5) Reporting serious or continuing noncompliance and Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs) to the U.S. Army Medical Research and Materiel Command Office of Research Protections Human Research Protections Office (USAMRMC ORP HRPO) and the Army Human Research and Protection Office (AHRPO) as per UWZ-C-636 on behalf of the IO.

b. The WRAIR IRB Chair or designee is responsible for:

- 1) Initial IRB review and assessment of major deviations and UPIRTSOs.
- 2) Recommending initial action on behalf of the IRB.
- 3) Referring all major deviations and UPIRTSOs to the WRAIR IRB, as appropriate, for review and determination.



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c. The WRAIR IRB is responsible for:

- 1) Reviewing and assessing the major deviations and UPIRTSOS, and the corrective action plan, as appropriate.
- 2) Determining whether or not UPIRTOS meet the reporting requirements as outlined in the OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events
- 3) Determining whether there is non-compliance by the investigator as per SOP UWZ-C-606, Non-Compliance Procedures.

d. The WRAIR Institutional Official (IO):

- 1) Reviews and approves/disapproves the disposition of major deviations and/or UPIRTSOs as summarized in the IRB minutes.
- 2) Under circumstances involving serious or continuing non-compliance, the IO may review the deviation prior to issuance of the IRB minutes, per the SOP UWZ-C-606, Non-Compliance Procedures.
- 3) Ensures action is taken if investigators do not adhere to the reporting requirements.
- 4) Requests DHSP to report serious or continuing noncompliance and UPIRTSOs to USAMRMC ORP HRPO and AHPRO as per UWZ-C-636, and to the relevant federal department or agency head on his behalf.

3. Investigator Guidance

The Principal Investigator (PI) is expected to:

- 1) Submit protocol deviation(s) as follows:
 - a. Major deviations must be promptly reported (within 48 hours upon becoming aware of the event) to the DHSP (using the Deviation/Unanticipated Problem Report Form, Appendix A, or a memorandum with similar content) and recorded in the study deviation log (refer to Appendix C). The PI is responsible for making the initial determination; however, guidance may be obtained from the DHSP office. A written report must be submitted within 10 working days of knowledge of the event to the DHSP.



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Major deviations may include, but are not limited to:

- i. Written consent not obtained or consent form missing;
 - ii. Therapy or protocol interventions initiated prior to consent;
 - iii. Inclusion or exclusion criteria deviation without IRB approval;
 - iv. Delayed reporting of Serious Adverse Events (SAEs), unexpected adverse events, or unanticipated problems;
 - v. Incorrect dosing of any study product; OR
 - vi. Pregnancy in studies for which pregnancy is strictly to be avoided.
- b. Minor deviations (deviations not considered to be major deviations) should be reported in the deviation log (refer to Appendix C) and reported to the IRB as part of the continuing review (see SOP UWZ-C-618, Continuing Review and Continuation Determination).

Minor deviations may include, but are not limited to:

- i. Study procedure conducted out of sequence;
- ii. Consent form not given to the person signing the form;
- iii. Subject's visit was outside of study window (less than 2 days)
- iv. Over-enrollment (depending on the nature of the study and the number enrolled);
- v. Failure to perform a required lab test and this lab test is not known to be adversely affected by the study intervention;
- vi. Failure of subject to return unused study drug.

Note: Any of the above listed deviations may be assessed as major deviations depending on the severity and frequency.

2) Submit unanticipated problems as follows:

- a. The WRAIR IRB requires prompt reporting of UPIRTSOs (using the Deviation/Unanticipated Problem Report Form, Appendix A) to the DHSP (within 48 hours) upon becoming aware of the event by telephone, facsimile, or email, and recording it in the study unanticipated problem log (refer to Appendix C). A written report is required to be submitted by the PI to the DHSP within 10 working days of knowledge of the event.
- b. All other unanticipated problems should be included in the deviation/unanticipated problem log and reported to the IRB as part of the protocol continuing review, as per the SOP UWZ-C-618, Continuing Review and Continuation Determinations.



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- 3) Respond to requests made by the DHSP, WRAIR IRB and/or WRAIR IRB Chair regarding the deviation(s) or unanticipated problems, no later than five (5) business days from the receipt of the request, unless either waived or modified by the Director, DHSP or the Chair, WRAIR IRB or designees. Failure to respond to a request may result in the initiation of non-compliance procedures as per the SOP UWZ-C-606, Non-Compliance Procedures;
- 4) Adhere to the Sponsor's reporting requirements and timelines in addition to those of other overseeing IRBs/ERCs, and the WRAIR IRB.

5. Procedures

a. DHSP staff:

- 1) Upon notification of a deviation or unanticipated problem via phone, email, facsimile, or written memorandum: make an initial assessment to determine if it meets the prompt reporting requirements and/or to determine if any harm to study participant(s) has/have or may have occurred. If the deviation or unanticipated problem meets either of these requirements, then immediately report it to the IRB Chair or designee for review;
- 2) Log the following information into the protocol database and assign it a major deviation/UPIRTSO number [numbers will be assigned sequentially (1, 2, 3, etc.) for each protocol and event (major deviation or UPIRTSO)];
 - a. Date of major deviation/UPIRTSO submission
 - b. Date of major deviation/UPIRTSO
 - c. Description of major deviation/UPIRTSO
 - d. Description of follow-up action taken (if any)
- 3) Assist the PI, as needed, to complete the Protocol Deviation/Unanticipated Problem Report Form (Appendix A);
- 4) Assess the deviation/unanticipated problem and request additional information from the PI, as necessary;
- 5) Upon receipt of the Protocol Deviation Report Form/ Unanticipated Problem, attach the Protocol Deviation/ Unanticipated Problem Report Action Sheet (Appendix B) and any other pertinent correspondence, and provide to the WRAIR IRB Chair or designee for consideration;
- 6) Relay to the PI any actions required in the wake of deliberations and judgments from the IRB Chair and/or the fully convened IRB;



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- 7) Archive a copy of the Protocol Deviation/Unanticipated Problem Report Form, the Protocol Deviation/ Unanticipated Problem Report Action Sheet, and copies of all communications and records relating to the event and its outcome;
- 8) For all major deviations and UPIRTSOs, notify the WRAIR IO and USAMRMC ORP HRPO upon receipt of the Protocol Deviation/Unanticipated Problem Report Form.
- 9) Notify the USAMRMC ORP HRPO and AHRPO of all UPIRTSOs determined by the WRAIR IRB to meet the reporting requirements as outlined in the OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, as per UWZ-C-636 on behalf of the IO.
- 10) Notify the USAMRMC ORP HRPO and AHRPO of any noncompliance issues that are determined to be serious or continuing noncompliance as per UWZ-C-636 on behalf of the IO.

b. The WRAIR IRB Chair or designee:

- 1) Upon notification of a major deviation/UPIRTSO, or receipt of a Protocol Deviation/Unanticipated Problem Report Form and Action Sheet, review the deviation/unanticipated problem and obtain further information from the PI, as needed;
- 2) Make one of the following determinations (as listed on the Protocol Deviation/Unanticipated Problem Report Action Sheet):
 - (a) Request more information;
 - (b) Approve the deviation/unanticipated problem report or summary as written, with no further action required;
 - (c) Accept the deviation/unanticipated problem report, with full approval contingent upon modification to the protocol/protocol-related documents and/or the submission of a corrective action plan; or
 - (d) Refer to full WRAIR IRB for further consideration.
 - (e) If the deviation is determined to not qualify as a major deviation, then it will be marked as 'Information Only Acknowledgement', returned to the PI and requested to be submitted with the deviation log at the time of continuing review.
 - (f) If the unanticipated event is determined not to be a UPIRTSO, then it will be marked as 'Information Only Acknowledgement', returned to the PI and



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requested to be submitted with the unanticipated problem log at the time of continuing review.

- (g) Specify whether or not any or all of the following parties should be notified of the deviation or unanticipated problem: WRAIR IO, USAMRMC ORP HRPO, and/or AHRPO.
 - (h) The WRAIR IRB Chair or designee can request that the DHSP Staff or WRAIR IRB Administrative Director make any of the required notifications specified in Procedures Section b (2)(g) of this document.
 - (i) Notify the relevant federal department or agency head for all UPIRTSOs determined by the WRAIR IRB to meet the reporting requirements as outlined in the OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events.
- 3) The WRAIR IRB review the major deviation/UPIRTSO and associated actions as forwarded by the IRB Chair and/or designee and either:
- (a) Accept the major deviation/UPIRTSO or summary as written;
 - (b) Request the PI to submit more information or a follow-up report to include a plan of action, as appropriate;
 - (c) Decide whether there has been non-compliance by an investigator in accordance with the SOP UWZ-C-606, Non-Compliance Procedures; and make a recommendation for course of action; Non-compliance determinations will be forwarded to the WRAIR IO for consideration in accordance with the SOP UWZ-C-606, Non-compliance Procedures;
 - (d) Specify whether or not any or all of the following parties should be notified of the deviation, non-compliance arising from the deviation, or UPIRTSO: WRAIR IO, USAMRMC ORP HRPO, AHRPO, and/or relevant federal department or agency head;
- c. The WRAIR IO:
- 1) Approve/disapprove the disposition of the major deviation/UPIRTSO and the action taken by the IRB.
 - 2) When appropriate, review and approve/disapprove corrective action plans.



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3) Request that the DHSP report serious or continuing noncompliance/UPIRTSO to USAMRMC ORP HRPO, AHRPO, and/or the relevant federal department or agency head on his behalf.



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6. Explanation of Abbreviations and Terms:

AHRPO	Army Human Research and Protection Office
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.
DHSP	Division of Human Subjects Protection; the administrative support of the WRAIR IRB.
ERC	Ethical Review Committee
Human Subjects Research	Research involving humans as research subjects, or involving biological specimens, data, specimens from repositories or anatomical substances of human origin. This includes the administration of questionnaires or surveys, as well as research done in an educational setting.
IO	Institutional Official
IRB	Institutional Review Board
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.
Minor Deviation	Protocol deviations that do not affect or do not potentially affect the health and welfare of study participants, and do not compromise the integrity of the results in such a way that the study objectives may not be achieved, although these may nonetheless affect the study results.



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ORP Office of Research Protection at United States Army Medical Research and Materiel Command

PI Principal Investigator and/or WRAIR POC

POC Point of Contact

SAE Serious Adverse Event

SOP Standard Operating Procedures

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.

UPIRTSO 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.

USAMRMC United States Army Medical Research and Materiel Command



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WRAIR IRB

WRAIR Institutional Review Board; the ethical review committee for research involving human subjects as per the cited regulations and policies at WRAIR, its detachments or Overseas Laboratories, or when WRAIR funding, facilities or personnel are involved in any way (i.e. investigator). This includes protocols for which recruitment of subjects is through WRAIR.



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7. References

Regulation No, SOP etc, if applicable	Document Title
32 CFR 219	Code of Federal Regulations, Protection of Human Subjects, 1991
21 CFR 56	Code of Federal Regulations, Institutional Review Boards, 1998
45 CFR 46	Code of Federal Regulations, Protection of Human Subjects, 2007
OHRP Guidance on UPIRTSOs	Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, 15 January 2007
USAMRMC ORP HRPO	Institutional Policies and Procedures, Version 1, April 2005. Human Research Protections Office, Office of Research Protections, USAMRMC
Command Policy 2011-67	Reporting Suspensions or Terminations of Institutional Review Board (IRB) Approval and Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) in Human Subjects Research Conducted or Supported by the U.S. Army Medical Research and Materiel Command
ALARACT	AHRIPO reporting requirements
WRAIR IRB Charter	WRAIR Institutional Review Board (IRB) Charter
WRAIR HRPP	WRAIR Human Research Protection Program (HRPP)
SOP UWZ-C-606	Non-Compliance Procedures
SOP UWZ-C-618	Continuing Review and Continuation Determination



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8. Forms and Appendices

Form or Appendix Number	Title
UWZ-C-621-A Appendix A	DHSP Protocol Deviation/Unanticipated Problem Report Form
UWZ-C-621-B Appendix B	DHSP Protocol Deviation/Unanticipated Problem Report Action Sheet
UWZ-C-621-C Appendix C	DHSP Protocol Deviation/Unanticipated Problem Log

9. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	Original document	17 Nov 2008
.01	Updated with unanticipated problems and reporting requirements due to rescinding both the WRAIR SOP, Ensuring Prompt Reporting to the HURC (UWZ-C-611) and the Guidance on Reporting Deviations to the WRAIR Division of Human Subjects Protection.	MAR 2 1 2011
.02	Clarified the reporting requirements for noncompliance and UPIRTSOs and added the reference to the Command Policy 2011-67.	NOV 0 2 2011



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Appendix A:	DHSP Protocol Deviation/Unanticipated Problem Report Form	SOP No. UWZ-C-621
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Protocol Deviation/Unanticipated Problem Report Form**

e-mail to: wrairdhsp@amedd.army.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, 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



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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/violation 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.



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DHSP Protocol Deviation/Unanticipated Problem Report Action Sheet

WRAIR Protocol #: _____

DHSP POC: _____

PI/WRAIR POC: _____

Sponsor: _____

Date Submitted for Review: _____

DHSP Office:

- Major Deviation
- Does Not Qualify as a Major Deviation
- UPIRTSO
- Does Not Qualify as a UPIRTSO
- Suspected Protocol Non-compliance (see SOP UWZ-C-606)

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): _____

Action Taken (check all that apply):

- Request for More Information: _____
- Information Only Acknowledgement
- Approved; no further action required
- Accepted; requires modification to protocol-related documents
- Refer to Full WRAIR IRB for: _____
- Notify IO
- Notify USAMRMC ORP HRPO



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- Notify USAMRMC ORP HRPO and AHRPO

- Notify Federal Agency or Department (Specify): _____

Signature: _____ Date: _____



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Division of Human Subjects Protection 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 Division of Human Subjects Protection (DHSP) 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 DHSP 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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Appendix C: DHSP Protocol Deviation/Unanticipated Problem Log	SOP No. UWZ-C-621
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Study Name:	Principal Investigator:
WRAIR Protocol Number:	PI or Study Coordinator Contact info:

SUBJECT INITIALS/ID#	DATE	Deviation?	MAJOR Deviation?	Unanticipated Problem?	UPIRISO?	Description of Event

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

Principal Investigator Signature

Date