



**WALTER REED ARMY INSTITUTE OF RESEARCH**  
**Division of Human Subjects Protection**  
**Standard Operating Procedure**



SOP Title	<b>AMENDMENTS TO HUMAN SUBJECTS RESEARCH PROTOCOLS</b>	SOP No.	UWZ-C-615
		Version	.02
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**Signatures and Dates:**

Author:

QA Review:

For signatures, please see  
original in the Division of  
Human Subjects Protection

Approving  
Authority:

Review/Approval for unchanged documents

Date	Author	QA Review	Approving Authority



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### 1. Purpose/Applicability

This Standard Operating Procedure (SOP) describes the procedures for submitting, reviewing, and approving an amendment to approved research involving human subjects.

This SOP applies to the Division of Human Subjects Protection (DHSP), the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB), and the WRAIR Commander also known as the WRAIR Institutional Official (IO).

### 2. Responsibilities

a. WRAIR DHSP staff members are responsible for:

- 1) Receiving an amendment and supporting documentation for review,
- 2) Providing technical assistance to Principal Investigators (PIs) on the required format and documentation of an amendment covered under this SOP,
- 3) Assuring the review of an amendment and documenting the review, and
- 4) Assuring that, if required, the amendment is forwarded to the WRAIR Standing Scientific Review Committee (SSRC) for scientific review and approval in accordance with WRAIR SOP UWZ-002, Scientific Review of Human Use Protocols.

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

- 1) Reviewing and recommending approval, if appropriate, of an amendment that qualifies for the expedited review procedure [21 CFR 56.110 (b), 32 CFR 219.110(b) and 45 CFR 46.110(b)], in accordance with this SOP,
- 2) Forwarding any amendment that increases risk to subjects or does not qualify for the expedited review procedure to the fully convened WRAIR IRB as outlined in Section 5(b).



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- c. The WRAIR IRB is responsible for reviewing and recommending approval, if appropriate, of an amendment to approved research, in accordance with this SOP.
- d. The WRAIR Commander/IO is responsible for:
  - 1) Approving an amendment for implementation or disapproving the request in accordance with this SOP, and,
  - 2) Officially transmitting the proposed amendment to the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Human Research Protection Office (HRPO) IF such approval is required for the amendment. Once USAMRMC HRPO approval is obtained, the WRAIR IO may provide authorization to implement.

**3. Investigator Guidance**

The Principal Investigator (PI) is expected to:

- a. Submit electronic versions of the protocol amendment and all supporting documentation to the DHSP for review via the DHSP email address (available on the Outlook Global Address List). Submission should include:
  - 1) a signed cover letter through the PI's Department/Division or Detachment Commander that describes and justifies the amendment and includes information about any change in the level of risk to human subjects,
  - 2) the revised protocol and any other applicable documents, e.g. the consent form, Volunteer Emergency Contact Card, etc. Both a tracked changes version and a clean copy of the revised document(s) need(s) to be submitted.
- b. Reply to any comments made by the DHSP, the SSRC, the IRB Chair or the fully convened IRB in a timely manner, until the amendment has been approved, disapproved or withdrawn. Note: This may include revising the submitted documents and resubmitting with new version numbers and dates.



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- c. Assure that the amendment has received IRB and WRAIR Commander/IO approval prior to implementation except in cases where there are immediate hazards to human subjects.
- d. Add the amendment and all documentation of review/approval to the official protocol.

#### **4. Procedures**

##### **a. The DHSP Staff**

- 1) Document receipt of the amendment according to WRAIR SOP, Submission of Human Subjects Research Protocols and Consent Forms for Review, UWZ-C-623.
- 2) Review the amendment to ensure the submission is complete, per the Submission Checklist (Refer to WRAIR SOP, Submission of Human Subjects Research Protocols and Consent Forms for Review, UWZ-C-623), and make an initial determination of the required level of scientific and ethical review.
- 3) Administrative changes, such as changes in telephone numbers, do not require scientific review.
- 4) If necessary, submit the protocol to the WRAIR SSRC in accordance with WRAIR SOP UWZ-002, Scientific Review of Human Use Protocols.
- 5) Submits the amendment to the IRB Chair (or designee), if it is eligible for expedited review; or schedules it for review at a meeting of the fully convened IRB. Note: If an amendment requires full IRB review, it will need to be reviewed by an IRB member prior to the meeting who can report on the amendment to the full IRB.
- 6) Notify the PI in writing of the following amendment review results:
  - a) approval – The IRB Chair or the convened IRB recommends approval to the Commander of WRAIR and the Commander approves the amendment for implementation.
  - b) request for additional revisions – A written request from the IRB Chair or the convened IRB for additional changes/information to resolve issues prior to further action.



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- c) disapproval – A written communication to the PI that includes the reason(s) for the disapproval.
- 7) Assure that the applicable authorizations (for example, a Food and Drug Administration exemption), agreements (for example, an IRB Authorization Agreement), and approvals (for example, local IRB approval) are in place prior to implementation approval.
  - 8) For an amendment that requires review by the USAMRMC HRPO, prior to implementation approval, submit a copy of the amendment and supporting documentation to USAMRMC HRPO for appropriate review and approval.
  - 9) If the approved amendment includes a revised consent document and the protocol is a CONUS study, stamp the consent document with an IRB approval stamp indicating the version number and expiration date (Refer to WRAIR SOP UWZ-C-635, Stamping of Protocol Materials).  
Note: For all amendments, approval is effective only until the expiration date of the most recent continuing review.
  - 10) Inform the IRB of amendments approved via the expedited review procedure by including a summary of the amendments approved in the IRB meeting materials.
  - 11) Maintain a copy of the amendment and documentation of the scientific and ethical review process in the protocol file. As appropriate, update the DHSP database.
  - 12) Include in the IRB and Commander approval letters a statement that no changes may be made to an approved protocol without prospective IRB re-review and approval;
  - 13) Provide guidance on this requirement to WRAIR investigators; and
  - 14) Post guidance regarding this requirement on the DHSP website.



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b. The Chair of the IRB (or designee):

- 1) Reviews the amendment and determine if it qualifies for the expedited review procedure permitted by 21 CFR 56.110 (b), 32 CFR 219.110(b) and 45 CFR 46.110(b) or requires review by the convened IRB (Refer to WRAIR SOP, Expedited Human Subjects Research Protocol Review, UWZ-C-613). Examples of changes that may qualify for expedited review are: adding or removing an investigator, changes in advertising, or routine closure of a study. Examples of changes that require full-board are: a significant change in the study design, or the addition of a procedure that increases the risk to subjects beyond those defined as minimal risk. The IRB Chair or IRB Administrative Director has the authority to schedule any amendment for full-board review if, in their judgment, such review is necessary.
- 2) Under the expedited review procedure, takes one or more of the following actions after amendment review:
  - a) Recommends approval of the amendment to the Commander of WRAIR.
  - b) Submits a written request to the PI for additional changes/information to resolve issues prior to further action.
  - c) Submits an amendment that, in their judgment, should be reviewed by the fully-convened IRB, instead of an expedited review, to a convened IRB meeting for review.
- 3) Determines whether the amendment potentially affects study volunteers and/or their willingness to continue or enroll in the study. If the proposed amendment affects the volunteers' willingness to participate in the study, requests that the PI add the new information to the consent document and that study participants be contacted and re-consented with the revised consent document.



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c. The WRAIR IRB:

- 1) Approve (with or without stipulations), table, or disapprove the amendment after review at a full-board meeting (Refer to WRAIR SOP, WRAIR IRB Meetings, UWZ-C-616).
- 2) Determine whether the amendment affects study volunteers and whether it might affect their willingness to continue or enroll in the study. If the proposed amendment may affect the volunteers' willingness to participate in the study, request that the PI add the new information to the consent document and study participants be contacted and re-consented with the revised consent document.
- 3) Ensure that the discussion of issues with respect to the amendment and the results of the voting are included in the IRB meeting minutes according to WRAIR SOP UWZ-C-625, WRAIR IRB Meeting Minutes.
- 4) Review of the expedited list and corresponding approval or review memorandums.





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- IRB** Institutional Review Board - a specially constituted review body established or designated by an entity to protect the welfare of human subjects.
- IRB Approval** The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
- Minimal Risk** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests.
- ORP** Office of Research Protection at the U.S. Army Medical Research and Materiel Command (USAMRMC)
- PI** Principal Investigator or WRAIR POC.
- POC** Point of Contact
- Research** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research.
- SOP** Standard Operating Procedure
- SSRC** The WRAIR Standing Scientific Review Committee – conducts scientific peer review to ensure that the proposed research is scientifically sound in its design and methods, feasible, and worthy of performance.
- WRAIR** Walter Reed Army Institute of Research



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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 CONUS detachments or Overseas Laboratories, or when WRAIR funding, facilities or personnel are involved in any way (e.g. Investigator). This includes protocols for which recruitment of subjects is through WRAIR. Formerly the WRAIR Human Use Review Committee (WRAIR HURC).

USAMRMC

U.S. Army Medical Research and Materiel Command



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**6. References**

<b>Reference Numbers or Author</b>	<b>Document Title</b>
21 Code of Federal Regulations (CFR) 56	Food and Drug Administration, Institutional Review Boards
32 Code of Federal Regulations (CFR) 219	Department of Defense, Protection of Human Subjects
45 Code of Federal Regulations (CFR) 46	Health and Human Services, Protection of Human Subjects
Bankert, E. A. and Amdur, R. J.	<i>Institutional Review Board Management and Function (2<sup>nd</sup> Edition)</i> . (2006). Boston: Jones and Bartlett Publishers.
AR 70-25	<i>Use of Volunteers as Subjects of Research</i> , 25 January 1990
WRAIR SOP UWZ-002	<i>Scientific Review of Human Use Protocols</i>
WRAIR SOP UWZ-C-614	<i>Expedited Review of Human Subjects Research Protocols</i>
WRAIR SOP UWZ-C-616	<i>WRAIR IRB Meetings</i>
WRAIR SOP UWZ-C-625	<i>WRAIR IRB Meeting Minutes</i>
WRAIR SOP UWZ-C-635	<i>Stamping of Protocol Materials</i>
OHRP	<i>Guidance on Written IRB Procedures</i> , 15 January 2007, <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm">http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm</a>



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**7. Forms and Appendices**

N/A

**8. Document Revision History**

Version Number	Brief Description of Changes	Effective Date
.00	New document	22 March 2007
.01	Updated names and titles, revised per new scientific review SOP, and updated policies and procedures	31 March 2009
.02	Biennial Review; updated for consistency with current policies/procedures.	<i>APR 06 2011</i>