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

SOP Title	**SUBMISSION OF HUMAN SUBJECTS RESEARCH PROTOCOLS AND SUPPORTING DOCUMENTS FOR REVIEW**	SOP No.	UWZ-C-623
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Signature On File

21 March 2012
Human Subjects Protection Branch (HSPB) — Date

22 March 2012
Quality Liaison — Date

22 MAR 12
Human Subjects Protection Branch (HSPB) — Date

Review/Approval for unchanged documents

	Author/Date	QA Review/Date	Approving Authority/Date
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1. **Purpose and Applicability**

This Standard Operating Procedure (SOP) provides the process for submission of new and revised protocols involving human subjects to the Walter Reed Army Institute of Research (WRAIR) Human Subjects Protection Branch for administrative review and triaging.

2. **Responsibilities**

a. WRAIR HSPB Staff is responsible for reviewing human subjects research protocol submissions in accordance with applicable WRAIR and Federal policies, procedures, and guidance, to ensure receipt of a completed protocol submission. The Staff are also responsible for assisting investigators for protocol development, review and approval, and to provide any technical assistance as to the required formatting and documentation of protocols.

b. WRAIR HSPB Director, Deputy Director, or designee is responsible for the review of all HSPB protocol evaluation forms (PEFs), also known as pre-reviews, and for forwarding the documentation to the WRAIR Institutional Review Board (IRB Chair) or designee for review and/or an ethical consultation, if applicable. The Director ensures that the HSPB staff is trained on and understands this SOP.

c. Investigator Guidance

Principal Investigators (PIs) are expected to:

1) Consult the following prior to protocol submission:

a) Branch Director (or Detachment Commander) and Department Chiefs (as applicable) for support of the protocol.

b) HSPB/WRAIR IRB to determine the approximate timeline for development, review and approval of a protocol, an initial risk assessment and to receive any technical assistance as to the required format and documentation for protocols.

c) The research site for feasibility and provide documentation of interaction.

d) The WRAIR Office of Research and Technology Applications (ORTA) to determine if any necessary business agreements are needed to initiate and complete the work.

e) The sponsor, if applicable, to confirm that the protocol and supporting documents to be submitted are the authorized, "published" version.

2) Ensure protocols and consent forms are written in compliance with Federal and the Department of Defense (DoD) regulations and guidelines.

3) Ensure appropriate and regular training pertaining to research involving human subjects and ensuring the research personnel (e.g., Associate Investigators, Coordinators, Lab Assistants, etc.) maintain current curriculum vitae and human subjects training certification (Refer to WRAIR Policy Letter #11-49, Initial and Continuing Human Subjects Protection Education and Training Requirements).

4) Prepare protocol and related documents for submission to the HSPB as per WRAIR Policy #12-05 by utilizing the Investigator and Branch Director Submission Checklist (Appendage to the Policy) and ensuring the following:

a) The protocol and supporting documents contain a version number and version date within the header/footer.

b) Protocols are written with the appropriate DoD-specific requirements. Sponsor and/or other protocol templates are acceptable provided that the DoD requirements are met.

c) Exempt protocols are written following the template provided on the WRAIR HSPB website. Other protocol templates are acceptable provided that the elements/requirements are met.

d) The protocol is vetted through the Branch Director (or Detachment Commander) and Department Chief (as applicable) and appropriate signatures and evidence of support are obtained (Appendix 1).

e) The Deputy Commander may allow waivers of the complete submission packet in extenuating circumstances on a case by case basis. A letter

with justification must be submitted for consideration and accepted at the discretion of the WRAIR Deputy Commander.

5) Submit the protocol packet electronically to the HSPB office, including the following:

   a) The completed and signed Investigator and Branch Director Submission Checklist.

   b) The signed submission memorandum, Appendix 1.

   c) Protocol packet, which includes all items checked by the PI on the Investigator and Branch Director Submission checklist and listed in the submission memorandum (Appendix 1).

   d) Documents should be submitted through the electronic HSPB mailbox, WRAIRHSPB@amedd.army.mil.

6) For projects where an investigator is intending to obtain a determination that the activity is not research or a determination of research not involving human subjects, please refer to WRAIR Policy Letter #12-09, Determination that an Activity is Research involving Human Subjects for submission requirements.

7) For submission of amendments to existing research protocols, please refer to WRAIR SOP, Amendments to Human Subjects Research Protocols, UWZ-C-615.

3. **Materials and Equipment**

WRAIR Policy Letter #12-05 Appendix 1, Investigator and Branch Director Submission Checklist

4. **Procedures**

a. Upon receipt of a new protocol, the HSPB staff is to:

b. Ensure the protocol has not been previously submitted to the WRAIR HSPB by cross referencing the protocol title in the database and logbook and log the protocol into the HSPB database, with an assigned protocol number.

c. Assign a HSPB Human Subjects Protection Scientist (HSPS) to review the protocol.

d. Send e-mail correspondence to the PI confirming receipt of the submission packet and identifying the WRAIR HSPB point of contact (POC) for the study.

e. Conduct an administrative review of the protocol packet to assure it adheres to the format and content specified.

f. Communicate to the PI any corrections/additions required for the submission to be considered complete.

g. Make a preliminary determination of whether or not the protocol is research, research involving human subjects, or exempt and, as appropriate, submit for scientific review as per WRAIR SOP, Scientific Review of Human Subjects Research and Select Exempt Studies and Research Not Involving Human Subjects, UWZ-002.

h. Once WRAIR scientific approval or concurrence is obtained, submit the protocol packet for PEF development as per WRAIR SOP, Conducting Initial Protocol Review for Human Subjects Research, UWZ-C-603.

i. Start an IRB regulatory file for the protocol.

j. Proceed to ethical review by the appropriate IRB(s) once PEF comments are adequately addressed (See UWZ-C-613 and/or UWZ-C-628, as appropriate)

5. **Explanation of Abbreviations, Acronyms, and Terms**

CONUS	Continental United States
DoD	Department of Defense
HSPB	Human Subjects Protection Branch, WRAIR, is the administrative support for the WRAIR IRB.
HSPS	Human Subjects Protection Scientist, Division of Human Subjects Protection
OCONUS	Outside the Continental United States

ORTA	Office of Research and Technology Applications
PI	Principal Investigator, the scientist of scholar with primary responsibility for the design and conduct of a research project.
POC	Point of Contact
SOP	Standard Operating Procedure
WRAIR	Walter Reed Army Institute of Research
Exempt	A protocol is exempt from Institutional Review Board when it meets the requirements set forth in 32 CFR 219.101 or 45 CFR 46.101.
Human Subjects Research	Research involving humans as research subjects, or involving biological specimens, 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.
Research	Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
WRAIR IRB	WRAIR Institutional Review Board, the ethical review committee for research involving human subjects at WRAIR its CONUS detachments or OCONUS Laboratories, or when WRAIR funding, facilities or personnel are involved in any way (investigator, consultant, collaborator, etc.). This includes protocols for which recruitment of subjects is being performed at WRAIR.

6. **References**

Reference Number or Authors	Document Title
32 Code of Federal Regulations (CFR) 219	Department of Defense, Protection of Human Subjects
45 CFR 46	Health and Human Services, Protection of Human Subjects
DoD Instruction 3216.02	Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
21 CFR 56	Food and Drug Administration, Institutional Review Board
AR 70-25	*Use of Volunteers as Subjects of Research, 25 January 1990*
WRAIR Policy Letter #11-49	*Initial and Continuing Human Subjects Protection Education and Training Requirements*
WRAIR Policy Letter #12-05	*Submission of Protocols Involving Human Subjects, Human Biological Materials, and/or Human Data for Scientific and Ethical Review*
WRAIR Policy Letter #12-09	*Determination that an Activity is Research involving Human Subjects*
OHRP	*Guidance on Written IRB Procedures, 15 January 2007, http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm*
WRAIR SOP UWZ-002	*Scientific Review of Human Subjects Research and Select Exempt Studies and Research Not Involving Human Subjects*
WRAIR SOP UWZ-C-603	*Conducting Initial Protocol Review for Human Subjects Research*

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WRAIR SOP UWZ-C-609	*Identification and Management of Conflicts of Interest*
WRAIR SOP UWZ-C-613	*Expedited Human Subjects Research Protocol Review*
WRAIR SOP UWZ-C-615	*Amendments to Human Subjects Research Protocols*
WRAIR SOP UWZ-C-628	*Review of Human Subjects Research by the Fully Convened WRAIR Institutional Review Board*

7. Appendices and Attachments

Appendix or Attachment Number	Title
UWZ-C-623-A-1	Submission Memo for PIs & Branch Directors

9. Document Revision History

Version Number	Brief Description of Changes	Effective Date
N/A	Original document (ORM-002)	5 November 2004
.00	Updated to reflect current policies and procedures	3 February 2010
.01	Biennial Update. This version reflects current policies and procedures.	

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Submission Memo for PIs & Branch Directors

MCMR-UWX-X Date

MEMORANDUM THRU

Department Chief, Department of (If Appropriate)

Director, Branch of

FOR Director, Human Subjects Protection Branch, Walter Reed Army Institute of Research, 503 Robert Grant Ave, Silver Spring, MD 20910-7500

SUBJECT: Submission of New Protocol (or Amendment) TITLE (Version, Date, WRAIR #)

1. Description of submission

2. List of items being submitted as attachments (with versions & dates)

3. As the PI, I will carry out the study as outlined in the attached protocol.

4. Please contact the undersigned by Outlook or at (301) 319-XXXX for any additional information.

PI (or WRAIR POC) Signature Block

Branch Director (or Detachment Commander) Approval

"I approve this protocol as written.

The study is:
- ✓ scientifically feasible & valid,
- ✓ militarily relevant, and
- ✓ has appropriate resources (funding, personnel, equipment, etc.).

Branch Director Signature Block