

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



SOP Title	<b>SUBMISSION OF HUMAN SUBJECTS RESEARCH PROTOCOLS AND SUPPORTING DOCUMENTS FOR REVIEW</b>	SOP No.	UWZ-C-623
		Version	.00
Effective Date	FEB - 3 2010	Page	1 of 8

**Signatures and Dates:**

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

**Review/Approval for unchanged documents**

	Author/Date	QA Review/Date	Approving Authority/Date
1			
2			
3			
4			

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



<b>SOP Title</b>	<b>SUBMISSION OF HUMAN SUBJECTS RESEARCH PROTOCOLS AND SUPPORTING DOCUMENTS FOR REVIEW</b>	<b>SOP No.</b> UWZ-C-623
		<b>Version</b> .00
<b>Effective Date</b>	<b>FEB - 3 2010</b>	<b>Page</b> 2 of 8

### **1. Purpose/Applicability**

This Standard Operating Procedure (SOP) provides the procedures for submission of new and revised protocols involving human subjects to the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB).

This SOP replaces ORM-002, Submission of Human Use Protocols and Consent Forms for Review.

### **2. Responsibilities**

- a. WRAIR DHSP 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 in the timeline for protocol development, review and approval, and to provide any technical assistance as to the required formatting and documentation of protocols.
- b. WRAIR DHSP Director, Deputy Director, or designee is responsible for the review of all DHSP protocol pre-reviews and for forwarding the documentation to the WRAIR IRB Chair (or designee) for review and/or an ethical consultation, if applicable. The Director ensures that the DHSP staff is trained on and understands this SOP.

### **3. Investigator Guidance**

Principal Investigators (PIs) are expected to:

- a. Consult the following prior to protocol submission:
  - 1) Division Director (or Detachment Commander) and Department Chiefs (as applicable) for support of the protocol.
  - 2) DHSP/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.

WALTER REED ARMY INSTITUTE OF RESEARCH

Division of Human Subjects Protection

Standard Operating Procedure



SOP Title	<b>SUBMISSION OF HUMAN SUBJECTS RESEARCH PROTOCOLS AND SUPPORTING DOCUMENTS FOR REVIEW</b>	SOP No.	UWZ-C-623
		Version	.00
Effective Date	<b>FEB - 3 2010</b>	Page	3 of 8

- 3) The research site for feasibility and provide documentation of interaction.
  - 4) The WRAIR Office of Research and Technology Applications (ORTA) to determine if any necessary business agreements, if any, are needed to initiate and complete the work.
  - 5) The sponsor, if applicable, to confirm that the protocol and supporting documents to be submitted are the authorized, "published" version.
- b. Ensure protocols and consent forms are written in compliance with Federal and the Department of Defense (DoD) regulations and guidelines.
- c. 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 vita and human subjects training certification (Refer to WRAIR Policy Letter #08-07, Initial and Ongoing Human Subjects Protection and Education).
- d. Prepare protocol and related documents for submission to the DHSP by utilizing the checklist provided (Appendix 1) and ensuring the following:
- 1) The protocol and supporting documents contain a version number and version date within the header/footer.
  - 2) Protocols are written with the appropriate DoD-specific requirements following the templates available on the WRAIR DHSP website. Other protocol templates are acceptable provided that the requirements outlined in the templates are met.
  - 3) Exempt protocols are written following the template provided on the WRAIR DHSP website. Other protocol templates are acceptable provided that the requirements outlined in the templates are met.
  - 4) The protocol is vetted through the Division Director (or Detachment Commander) and Department Chief (as applicable) and appropriate signatures and evidence of support are obtained (Appendix 2).
  - 5) The DHSP 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 IRB Chair or WRAIR IRB Administrative Director.

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



SOP Title	<b>SUBMISSION OF HUMAN SUBJECTS RESEARCH PROTOCOLS AND SUPPORTING DOCUMENTS FOR REVIEW</b>	SOP No.	UWZ-C-623
		Version	.00
Effective Date	<b>FEB - 3 2010</b>	Page	4 of 8

- e. Submit the protocol packet to the DHSP office, including the following:
- 1) The completed and signed checklist, Appendix 1.
  - 2) The signed submission memorandum, Appendix 2.
  - 3) Protocol packet, which includes all items checked by the PI on the checklist (Appendix 1) and listed in the submission memorandum (Appendix 2).
  - 4) One hard copy of all documents if an electronic copy cannot be submitted.
  - 5) Electronic documents should be submitted through the electronic DHSP mailbox, [WRAIRDHSP@amedd.army.mil](mailto:WRAIRDHSP@amedd.army.mil).
- f. 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 #08-03, Determination that an Activity is Research Involving Human Subjects for submission requirements.
- g. For submission of amendments to existing research protocols, please refer to WRAIR SOP, Amendments to Human Subjects Research Protocols, UWZ-C-615.

#### **4. Materials and Equipment**

N/A

#### **5. Procedures**

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

- a. Ensure the protocol has not been previously submitted to the WRAIR DHSP by cross referencing the protocol title in the database and logbook and log the protocol into the DHSP database, with an assigned protocol number.
- b. Assign a DHSP Human Subjects Protection Scientist (HSPS) to review the protocol.
- c. Send e-mail correspondence to the PI confirming receipt of the submission packet and identifying the WRAIR DHSP point of contact (POC) for the study.
- d. Conduct an administrative review of the protocol packet to assure it adheres to the format and content specified.

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



<b>SOP Title</b>	<b>SUBMISSION OF HUMAN SUBJECTS RESEARCH PROTOCOLS AND SUPPORTING DOCUMENTS FOR REVIEW</b>	SOP No. UWZ-C-623
		Version .00
Effective Date	<b>FEB - 3 2010</b>	Page 5 of 8

- e. Communicate to the PI any corrections/additions required for the submission to be considered complete.
- f. 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 Use Protocols, UWZ-002.
- g. Once scientific approval is obtained from the WRAIR Office of the Science Director (WOSD) or Chair, Standing Scientific Review Committee (SSRC), submit the protocol packet for ethical review as per WRAIR SOP, Conducting Initial Protocol Review, UWZ-C-603.
- h. Start a study file for the protocol.

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

Conflict of Interest (COI)	Situation in which financial or other personal situations may compromise, or have the appearance of compromising an Investigator's or IRB Member's professional judgment in conducting, reporting or reviewing research. See WRAIR SOP, Identification and Management of Conflicts of Interest, UWZ-C-609.
CONUS	Continental United States
CRADA	Cooperative Research and Development Agreement
DSMB	Data and Safety Monitoring Board
DoD	Department of Defense
DHSP	Division of Human Subjects Protection, WRAIR, is the administrative support for the WRAIR IRB.
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.
FDA	U.S. Food and Drug Administration



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



SOP Title	<b>SUBMISSION OF HUMAN SUBJECTS RESEARCH PROTOCOLS AND SUPPORTING DOCUMENTS FOR REVIEW</b>	SOP No.	UWZ-C-623
		Version	.00
Effective Date	<b>FEB - 3 2010</b>	Page	6 of 8

HSPS	Human Subjects Protection Scientist, Division of Human Subjects Protection
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.
IDE	Investigational Device Exemption
IND	Investigational New Drug
ORTA	Office of Research and Technology Applications
OCONUS	Outside the Continental United States
POC	Point of Contact
PI	Principal Investigator, the scientist or scholar with primary responsibility for the design and conduct of a research project.
RAC	Recombinant DNA Advisory Committee
Research	Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
SMC	Safety Monitoring Committee
SSRC	Standing Scientific Review Committee
SOP	Standard Operating Procedure
SFA	Support Facility Annex
USAMRMC	U.S. Army Medical Research and Materiel Command



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



SOP Title	<b>SUBMISSION OF HUMAN SUBJECTS RESEARCH PROTOCOLS AND SUPPORTING DOCUMENTS FOR REVIEW</b>	SOP No.	UWZ-C-623
		Version	.00
Effective Date	FEB - 3 2010	Page	8 of 8

WRAIR SOP UWZ-002	<i>Scientific Review of Human Use Protocols</i>
WRAIR SOP UWZ-C-609	<i>Identification and Management of Conflicts of Interest</i>
WRAIR SOP UWZ-C-615	<i>Amendments to Human Subjects Research Protocols</i>

**8. Forms and Appendices**

Form or Appendix Number	Title
UWZ-C-623-A-1	Required Documents for Submission Checklist
UWZ-C-623-A-2	Submission Memo for PIs & Division 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	