



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



SOP Title:	REVIEW OF HUMAN SUBJECTS RESEARCH BY THE FULLY CONVENED WRAIR INSTITUTIONAL REVIEW BOARD	SOP No. UWZ-C-628
		Version .01
Effective Date	MAR 27 2013	Page 1 of 9

Signatures and Dates:

Author:

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

Approving
Authority:

Change Control: 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 process the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) members use when reviewing human subjects research protocols at fully convened IRB meetings. The procedure outlined in this SOP applies to initial protocol submissions and life cycle actions (amendments, continuing review reports, safety reports, protocol deviations, etc.). For the purpose of this SOP, "protocol submission" means the complete study documentation to include the protocol, consent document, and supporting material (see SOP UWZ-C-623, Appendix A, *Required Documents for Submission Checklist*). This SOP also provides criteria to use when reviewing protocols.

This SOP applies to the Division of Human Subjects Protection (DHSP) Staff and WRAIR IRB members. The WRAIR IRB uses a primary reviewer system. That is, 1-2 members serve as primary reviewers to review the protocol packet and discuss any concerns with the Principal Investigator (PI) or protocol Point of Contact (POC), facilitate discussion at the meeting, and prepare a motion. All WRAIR IRB members are expected to review all materials submitted for the WRAIR IRB meeting.

2. Responsibilities

a. WRAIR DHSP staff members are responsible for:

- 1) Reviewing this SOP,
- 2) Determining that a packet is complete and all the required elements (as specified in SOP UWZ-C-623) are included for review by the WRAIR IRB Chair, who will determine if the study should be reviewed by the full board or can undergo expedited review. This is done in coordination with Human Research Protections Office (HRPO), U.S. Army Medical Research Materiel Command (USAMRMC) review, as appropriate,
- 3) Assisting with the assignment of primary and secondary reviewers. and,
- 4) Communicating questions, comments, suggestions to the PI and/or to facilitate communication of questions by the IRB reviewers or chair with the PI, or protocol POC, in order to address any questions in advance of the meeting.

b. WRAIR IRB members are responsible for:

- 1) Reviewing this SOP,
- 2) Reviewing each action item on the WRAIR IRB meeting agenda,
- 3) Being prepared to discuss agenda items at full board and subcommittee meetings,



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- 4) Serving as primary or secondary reviewers,
- 5) Communicating with the PI or protocol POC to address any questions in advance of the meeting, and
- 6) Presenting a motion at the IRB meeting.

c. WRAIR IRB Chair or designee in addition to part b is responsible for:

- 1) Assigning primary and secondary reviewers (in coordination with IRB Administrative Director),
- 2) Determining that a packet is complete and ready for review by the WRAIR IRB, by either the full board or expedited review process, and, 3) For protocol submissions, review of minor changes requested by the WRAIR IRB, and life cycle actions that qualify for expedited review, reviewing and approving protocol submissions specified in SOP UWZ-C-613, in accordance with this SOP.

3. Investigator Guidance

a. The PI or protocol POC should:

- 1) Provide a complete protocol packet or documentation of life cycle action to the DHSP in accordance with WRAIR SOP UWZ-C-623,
- 2) Answer questions from DHSP/HRPO, USAMRMC reviewers, and IRB/Research Ethics Advisory Panel (REAP) members regarding the protocol submission. and,
- 3) Attend (via phone or in-person), if requested, the WRAIR IRB meeting at which the protocol is reviewed to discuss any important issues that could not be resolved before the meeting. For the regulations on IRB membership and who may be present at IRB meetings, see HHS 45 CFR 46.107 (f), FDA 21 CFR 56.107 (f), or DoD Directive 3216.2 Section 4.3.2).

4. Procedures

a. DHSP staff is expected to:

- 1) Ensure that scientific approval of the protocol is obtained.
- 2) Check that the Protocol Evaluation Form (PEF) (either DHSP or DHSP/HRPO combined review) has been completed and conveyed to the PI, and issues



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required by regulations and policies (see references) are addressed prior to full board IRB review.

- 3) Review the protocol submission packet to determine completeness (per the SOP UWZ-C-623) and the required elements as specified in SOP UWZ-C-603 are included.
 - 4) Outstanding items should be noted and conveyed to the IRB Administrative Director or the WRAIR IRB Chair, who will determine if the submission is sufficient for WRAIR IRB review.
 - 5) As DHSP point of contact (POC) for the protocol, maintain regular communication with the PI and the WRAIR IRB, answer questions and facilitate communication between the PI and the WRAIR IRB Chair through the DHSP Director in order to resolve controversial issues prior to WRAIR IRB meetings, as appropriate.
 - 6) Assist the WRAIR IRB Chair with assignment of primary and secondary reviewers - This is to be based on expertise, availability, conflicts of interest, as well as other considerations.
- b. WRAIR IRB members (to include the IRB Chair) are expected to:
- 1) Review all protocol actions in their entirety, and contribute to the discussion of protocol actions at the full board meeting, as needed.
 - 2) Serve as primary and secondary reviewers for protocol submissions. Promptly notify the DHSP if they cannot fulfill their duties as assigned.
- c. Primary or secondary WRAIR IRB reviewers are expected to:
- 1) Conduct a thorough review of the protocol by using worksheets/checklists (Appendices A-C for new protocols) to aid in evaluating the protocol submission and explaining the protocol to other IRB members. Alternate but equivalent worksheets may be used. Worksheets for Continuing Review are found in WRAIR SOP UWZ-C-618. Reviewer worksheets are not collected as part of the IRB record. However, these may be used to supplement the documentation of the meeting minutes.
 - 2) Complete the review of assigned material at least two days before the full board sub-committee meeting and contact the investigator to resolve significant



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- questions/concerns before the meeting. The investigator's response should be in writing and copied to the DHSP POC.
- 3) Inform the WRAIR IRB Chair and WRAIR IRB administrator, before the meeting, of significant concerns about the protocol that may require additional discussion time or subcommittee review.
 - 4) As primary reviewer, present a brief summary (~5 minutes) of the protocol submission at the meeting, ending with issues that are unresolved or require discussion or action. As secondary reviewer, indicate agreement or disagreement with the primary reviewer's assessment, with a brief explanation of the rationale for any disagreement. The secondary reviewer adds or clarifies information.
 - 5) Ensure all criteria for IRB approval of research are covered as detailed in 45 CFR 46.111, 32 CFR 219.111, and/or 21 CFR 56.111, as appropriate.
 - 6) After discussion of the submission, make a recommendation regarding the vote on the protocol (for example, approve, disapprove, or defer/table; risk level, continuing review period, etc.).



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5. Explanation of Abbreviations and Terms

Best Practices	Good Clinical Practice (GCP) and International Conference on Harmonisation (ICH) Guidelines
DHSP	Division of Human Subjects Protection, WRAIR, the administrative office assisting the WRAIR IRB
GCP	Good Clinical Practices
HRPO	Human Research Protections Office, Office of Research Protections, Medical Research & Materiel Command
IRB	Institutional Review Board - a specially constituted review body established or designated by an entity to protect the welfare of human subjects.
Packet	Meeting Materials submitted to the WRAIR IRB for review
PEF	Protocol Evaluation Form (see appendix of UWZ-C-603, Conducting Initial Review of Human Subjects Research)
PI	Principal Investigator - the scientist or scholar with primary responsibility for the design and conduct of a research project.
Primary Reviewer System	The primary reviewer system means that a limited number of IRB members are assigned to conduct a detailed review of each protocol to be reviewed at the full committee meeting and present a summary of the study and any outstanding issues to facilitate discussion with all members.
Protocol Submission	Human subjects research protocol materials submitted for review
REAP	Research Ethics Advisory Panel, Medical Research and Materiel Command, a headquarter USAMRMC advisory panel to the Commanding General, USAMRMC, USAMRMC research leaders and the Director, HRPO on complex ethical and regulatory issues for selected studies or categories of research.
SOP	Standard Operating Procedure



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WRAIR

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WRAIR IRB

The WRAIR Institutional Review Board (IRB), an ethical review committee for review and approval of research involving human subjects at WRAIR, its CONUS detachments or Overseas Laboratories, or when WRAIR funding, resources and facilities, or personnel are involved in any way (investigator, medical monitor, consultant, collaborator, etc.). This includes protocols for which recruitment of subjects is through WRAIR.

USAMRMC

United States Army Medical Research and Materiel Command



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6. References

	Document Title
32 Code of Federal Regulations (CFR) 219	Department of Defense, Protection of Human Subjects
21 CFR 56	Food and Drug Administration, Department of Health and Human Services, Institutional Review Boards
45 CFR 46	Health and Human Services, Protection of Human Subjects
	Bankert, E. A. and Amdur, R. J. (2006). <i>Institutional Review Board Management and Function</i> . Boston: Jones and Bartlett Publishers.
AR 70-25	<i>Use of Volunteers as Subjects of Research, 25 January 1990</i>
WRAIR Policy Letter #08-03	<i>Procedures for the Review of Protocols Involving the Use of Humans as Volunteer Research Subjects</i>
	Amdur, R. J. (2010). <i>Institutional Review Board Member Handbook</i> . Boston: Jones and Bartlett Publishers.
DODD 3216.02	Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
Command Policy Memorandum 2010-10	Medical Care for Research Related Injury
SOP UWZ-C-623	Submission of Human Subjects Research Protocols and Supporting Documents for Review
SOP UWZ-C-610	Voting Requirements
SOP UWZ-C-613	Expedited Human Subjects Research Protocol Review
SOP UWZ-C-616	WRAIR IRB Meetings
SOP UWZ-C-603	Conducting Initial Protocol Review
SOP UWZ-C-618	Continuing Review and Continuation Determination



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7. Forms and Appendices

Form or Appendix Number	Title
Appendix A	WRAIR IRB Protocol Worksheet
Appendix B	WRAIR IRB International Research Worksheet
Appendix C	WRAIR IRB Primary Reviewer Worksheet

8. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	New document	8 February 2008
.01	Biennial review to include updates for consistencies with current policies and procedures.	MAR 21 2011

WRAIR IRB PROTOCOL WORKSHEET

1. Objectives, Background, and Significance

- Are the objectives clearly described?
- Does it appear that there is adequate preliminary data to justify the research?
- Does it appear that there is appropriate justification for this research protocol?
- Is the Principal Investigator(s) qualified by experience, training, etc.?
- Are there any notable conflicts of interest (Monetary, IP, etc)?
- Was scientific review approval achieved? If yes, did the scientific review identify any issues?

2. FDA/European Medicines Agency (EMA)/Environmental Protection Agency (EPA) - Regulated Research

- Is the regulatory status of the drug, device or biologic described and appropriate?
- Are the dose and route of administration appropriate?
- Request current status of the submission to the FDA/EMA.
- Documentation that FDA has issued an IND, IDE, etc to proceed with the study(s).
- Are the safety and efficacy data for the drug, device or biologic sufficient to warrant the proposed phase of testing?
- Is the risk status of the device (significant risk or nonsignificant risk) described and appropriate? Does the reviewer agree with the designation?
- Does the protocol describe acceptable accountability, storage, access, and control of the device?
- Is the Investigator Brochure (IB) current?
- Are there adequate provisions for monitoring the data (Data Safety Monitoring Board/Plan)? Is the charter included?

3. Study Design

- Does the study design appear to be adequate to meet the objectives?
- Are the objectives appear to be likely to be achieved in the specified time period?
- Does it appear that the study design is adequately described and justified?
- Are there appropriate resources (e.g. equipment, space, funding, staff) to conduct this study safely?

- Are staggered enrollments/administration of products appropriate?

4. Study Procedures

- Are study procedures adequately described and acceptable?
- Are research and non-research (e.g. clinical, established effective treatment) procedures clearly differentiated?
- Are there adequate plans to inform participants about specific research results that could affect the participant's health and/or decision to continue participation?

5. Enrollment Criteria

- Is subject selection equitable?
- Are inclusion and exclusion criteria clearly stated and reasonable?
- Are special classes of participants, especially populations deemed vulnerable (e.g. women (pregnant or of childbearing potential), children) included in the research? Is the inclusion or exclusion of special populations justified?
- If applicable, are pregnancy testing and contraceptive practices adequately addressed?

6. Data Analysis, Data Monitoring, & Data Safety

- Does it appear that the rationale for the proposed number of subjects is clearly stated and reasonable? Does it appear that formal sample size calculations were done and are they available for review?
- Are the plans for data analysis described and justified, including the use of stopping rules and endpoints, as they relate to human subjects protection?
- Are there adequate provisions for monitoring the data (Data Safety Monitoring Board/Plan)? Is the charter included? Will the IRB receive "regular" reports from the DSMB/DMC?
- Is a Medical Monitor needed for this study? If yes, is the person suggested appropriately trained (and available- per PI)?
- Are adverse event and unanticipated problems reporting addressed?

7. Subject Privacy and Confidentiality

- Are provisions to protect the privacy and ensure the confidentiality of research participants clearly described and adequate?

- Are plans and provisions to protect the confidentiality of data/specimens during and after the study described and adequate? (Who will have access, what will be stored, how long, any sharing, & where will data/specimens be stored/located?)
- Is use of identifiers or links to identifiers justified and how is this information protected? Are these measures adequate?
- Are measures for disposition/management of data/documents/specimens adequate?

8. Recruitment

- Are the methods for recruiting volunteers adequately described and appropriate? (Have all flyers, briefing slides, PPTs, etc. been provided?)
- Are the amount and type of payment or reimbursement adequately described and do they have a potential to cause undue influence? Is the total amount on flyer? Is this appropriate given the study population?
- Are the location and timing of recruitment activities acceptable?
- Are the individuals conducting recruitment activities appropriate?
- If applicable, are acceptable methods in place for screening participants before recruitment (e.g. mailings, medical records review)?

9. Subject Payment/Reimbursement and Costs

- Is the amount and type of payment or reimbursement clearly described, appropriate, and does not appear to have potential for undue influence?
- If study participation involves out of pocket expenses and/or cost to the participant if insurance denies payment, is this expense justified and clearly explained in the consent form?
- Are participants unduly influenced to accept increased cost?
- Do incentives have the potential to cause undue influence (examples: bonuses, referral payment)

10. Potential Risks/Discomforts and Benefits for Subjects

- Are the risks (relative to non-research alternative) and benefits (direct for the subject versus altruism) clearly identified and described?
- Risk:Benefit Ratio Analysis: Do the benefits to be gained justify the risks? Does the knowledge to be gained justify the risks?
- Have potential risks been minimized as much as possible by:
 - (a) Using procedures consistent with sound study design (e.g. appropriate control group),

- (b) Using procedures that do not necessarily expose subjects to risk, and
- (c) Using procedures already being done on subjects for diagnostic/treatment purposes?
- What risk designation should the study be given (minimal risk versus greater than minimal risk)?
- Is there intent to benefit vulnerable participants (e.g. children)?
- Are special protections in place for vulnerable participants?
- Has the investigator described an appropriate plan for monitoring participants during and after the research? If applicable, will counseling, referrals, or other support services be provided?
- GTMR Studies Only (where the PI is a USAMRMC employee or the site is a USAMRMC laboratory) - Has the medical care for research related injury been addressed in the protocol and consent?

11. Informed Consent/Assent

- Is the informed consent process adequately described?
- Does the process provide sufficient privacy, time and an adequate setting for the subject to consider participation?
- Does the process minimize the possibility of coercion or undue influence?
- Is the appropriate individual obtaining informed consent/assent?
- Does the informed consent document contain the required elements (see WRAIR IRB Consent Form Checklist, Appendix D)?
- Does the information in the consent form match what is in the protocol?
- Is the consent form likely to be understood by the expected subject population?
- Are future uses of data/specimens addressed (example: genetic testing)?
- Will photographs, video, or audio recordings be made?
- Is population literate? If not, what are provisions?
- Are subjects incapacitated? If yes, who are appropriate legally authorized representatives/surrogates?
- Is assent required? If so, is a separate assent form required?
- For parental consent, does the protocol describe:
 - (a) The age of majority for the minor population,
 - (b) What will happen if the parents consent and the child disagrees,
 - (c) Whether the signature of one or both parents is required if the subject is unable to consent.
- If the information that is given to the subject or the representative does not appear to be in language understandable to the subject or the representative, has a test of comprehension been provided?

12. Waiver or Modification of Informed Consent for Minimal Risk Research

- Have the criteria for a waiver of documentation of informed consent been met? Criteria are:
 1. The consent form is the only record linking the participant to the research and a potential risk would be a breach of confidentiality
OR
 2. Study involves no procedures for which written consent is normally required outside the research context. The participants decide if they want documentation.
- If the research includes children, have the criteria for a waiver of parental/guardian consent been met? Criteria are:
 1. Parental consent is not a reasonable requirement to protect child participants.
 2. Appropriate measures will be implemented to protect child participants.
- If waiver or modification of required consent elements was proposed, have all the criteria been met? Criteria are:
 1. Waiver/alteration will not adversely affect the rights and welfare of the participants.
 2. Research could not be practicably carried out without the waiver or alteration, and when appropriate, the participant will be given relevant information after participation.

13. Other Potential Reviews

- Institutional Biosafety Committee (IBC)
- Recombinant Advisory Committee (RAC)/OBA
- IACUC
- Radiation Safety Committee (Aka- RDRC)
- Other

14. Other Issues and Considerations

- Are there any outstanding pre-review considerations?
- For studies involving military personnel, have the DoD requirements been met (e.g. ombudsman, confidentiality qualifier, compensation requirement, etc. per 32 CFR 219 and DODD 3216.02)?
- For international research, have applicable items in Appendix B been addressed?
- For studies involving genetic testing/tissue repository, will the participants or their doctors be given research results? Are they informed of this before enrolling?
- When should the next review occur? Should it occur more frequently than annually?
- Is future use of specimens/data addressed?

WRAIR IRB International Research Worksheet

Protocol Title: _____

Country in which study is to be conducted: _____

A) Was a rationale provided for conducting research at this foreign site? ___ Yes ___ No

B) Foreign Study Site:

1. Is there an Assurance of compliance with human subjects protection regulations:
___ Yes ___ No

Type of Assurance: ___ DOD ___ HHS/OHRP ___ Other

Assurance No.: _____

Assurance Expiration Date: _____

Regulations the institution is required to follow, as per the Assurance: (e.g. ICH, CIOMS): _____

2. Name of study site's ethics committee: _____

Point of contact: _____

Contact information (phone number, email address, etc): _____

3. Review required by other institutions, offices, departments (e.g. Ministry of Public Health, Drug/Device oversight agencies): ___ Yes ___ No

If yes, provide name(s)/contact information: _____

4. Site PI name: _____

Contact information (telephone number/email): _____

5. Research team roles adequately described? ___ Yes ___ No

6. Documentation of training in human subjects' protection provided? ___ Yes ___ No

7. Provide a brief description of performance site (hospital, clinic, Clinical Research Organization, etc.)

8. Are there sufficient staff and facilities to conduct the research? Yes No

C) Was a local Scientific Review conducted? Yes No

1. Name of local committee/body who conducted scientific review provided?

Yes No

D) Was adequate information provided about the following items?

1. Description of the target population Yes No

- Legal age for individual to provide own consent to participate in research
- Ethnic composition
- Literacy and level of education
- Language/dialects spoken
- Economic issues (typical occupation(s), living conditions, wages/average income, cost of living, income factors, etc)
- Structure of community and family

2. Description of the local standards of health care for condition/disease under study, and the established effective therapy. Usual access to care and availability of health insurance was addressed.

Yes No

3. Description of this research in relation to the health care needs of the local site.

Yes No

4. Description of the post study plan for care/referral/medications/other.

Yes No

5. Description of medical care that will be available in the event of a research-related injury was provided. Yes No

Is this consistent with the current MRMC Policy? Yes No

6. The risk/benefit ratio was described in the social context and cultural norms of the local community. The PI considered the individual, family, community benefits, and any additional benefits for subjects at this site. Yes No

7. Unique recruitment strategies/processes for this site were identified.

Yes No

8. Describe the consent process, including the standard methods of consent (community consent, tribal elder consent, husband, use of information sheet, etc. as applicable). Explain how the research team will ensure informed consent is obtained.

-
9. If minors are the targeted study population, a description of assent/parental permission processes was provided. Yes No
10. If compensation is being offered, a justification was provided and explained in terms of average wage. Yes No
11. Will samples be taken out of the country for analysis, etc? Yes No
- Is this explicitly stated in the consent form? Yes No
12. Are there unique data and/or specimen management issues for this foreign site?
 Yes No
- If there are unique issues, the PI described them adequately and provided a plan for dealing with them. Yes No
13. Is there potential for the outcomes of the research negatively or positively impact the host community? Yes No
- If yes, describe: _____

Note: This OPTIONAL sample template lists the main issues and questions that you should consider and evaluate during review of the protocol. Its purpose is to help you organize the review and remember what issues have and have not been addressed during the WRAIR IRS's review of the protocol, and for presenting the review to fellow HURC members at the start of the protocol's discussion. The most applicable Belmont Report principle is included next to each review item.

WRAIR Institutional Review Board

Primary Reviewer Worksheet

1. Purpose of study:
2. Summary (Background, number of arms, controls, IND, etc.):
3. Investigator(s) (Qualified? Conflict of interest?) [Beneficence] :
4. Study population and recruitment practices:
 - Includes vulnerable subjects? (Children, etc.) [Respect for Persons]
 - Subject recruitment (Who, where, how?) [Beneficence]
 - Payment or reimbursements (Coercive?) [Beneficence]
 - Is subject selection likely to be equitable? [Justice]
 - Adequacy of procedures to protect vulnerable subjects [Respect for Persons]:
5. Informed consent process (written, surrogate, etc.) [Respect for Persons] :
6. Birth control [Beneficence] :
7. Genetic testing/tissue repository [Respect for Persons and Beneficence] :
 - Will the subjects or their doctors be given research results?
 - Are they informed of this before enrolling?
8. Cost (Relative to non-research cost):
 - Will subjects understand increased cost? [Respect for Persons]
 - Are subjects coerced to accept increased cost? [Beneficence]
9. Risks (relative to non-research alternative) [Beneficence] Rate risk level as (1) minimal, (2) moderate, or (3) high:
 - Absolute Relative
 - Risks are minimized (appropriate control group?)

10. Potential benefit (direct for the subject versus altruism):
11. Risk/benefit analysis [Beneficence]:
Risks are minimized and reasonable in view of potential benefits.
12. Confidentiality [Respect for Persons]:
Provisions to protect privacy and confidentiality are adequate.
13. Data oversight [Beneficence] How will data be monitored?
How will data be monitored?
Stopping rules are explained and sufficiently detailed.
14. Consent document [Respect for Persons]
Accurately describes the essential elements in a way that is likely to be understood by the expected subject population
15. Primary Reviewer's recommendation for approval: