



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



SOP Title	<b>INSTITUTIONAL REVIEW BOARD (IRB) MEETINGS</b>	SOP No.	<b>UWZ-C-616</b>
		Version	<b>.02</b>
Effective Date	<b>MAR 21 2011</b>	Page	1 of 10

**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) documents the procedures for the conduct of Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Meetings.
2. **Responsibilities:** This SOP applies to all Division of Human Subjects Protection (DHSP) staff, IRB members and the IRB Chair.
  - a. DHSP staff:
    - 1) Prepare a schedule of meetings for the following calendar year.
    - 2) Reserve the meeting room through the Department of Medical Audio and Visual Services.
    - 3) Arrange a pre-meeting with the IRB Chair or Acting Chair, as requested.
    - 4) Distribute the schedule to IRB members and WRAIR Investigators, as well as post the schedule on the website.
    - 5) Ensure each IRB member receives all pertinent review materials prior to the meeting.
    - 6) Provide notification to the IRB members and DHSP staff the week in advance of each scheduled meeting.
    - 7) Prepare meeting minutes in accordance with the WRAIR SOP UWZ-C-625, WRAIR IRB Meeting Minutes.
  - b. IRB Members:
    - 1) Review all distributed items and be prepared to discuss these items at the meeting.
    - 2) Notify the IRB Administrative Director (or his/her designee) or other point of contact with their confirmation of attendance.
    - 3) If unable to attend, notify the IRB Administrative Director (or his/her designee) or his/her alternate to attend the IRB meeting.
3. **Materials and Equipment:** Not Applicable.



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4. **Procedures:** WRAIR IRB meetings are held monthly, unless additional meetings are deemed necessary by the IRB Administrative Director or designee (and/or IRB Chair) in order to complete the review process of submitted studies. The frequency of meetings is determined by the IRB workload, availability of members and the research review interval(s) for studies under review.

a. Meetings

- 1) Meeting time: WRAIR IRB Meetings are generally held monthly, on the second Wednesday at 0900 hours.
- 2) Meeting location: WRAIR IRB Meetings are held at Building 503, WRAIR.
- 3) Scheduling: Generally, in October of each year.

Regular Meeting Requirements:

A quorum and a non-scientist must be present for a meeting to convene.

b. Meeting agenda

- 1) Preparation of the agenda may include a list of the following items: minutes from previous meetings, new protocols, continuing reviews, deviation reports, serious adverse event reports, expedited review list, educational material for the IRB and other items determined to need review/acknowledgement as decided by the IRB Administrative Director and/or IRB Chair.
- 2) Meeting materials referred to as "packets" are distributed approximately 7 days prior to the meeting date. All IRB members have access to electronic copies.

c. Protocols/Items for review

It is expected that protocols for review be in final form, when appropriate, incorporating changes requested from the DHSP pre-review, and have obtained scientific approval prior to submission to the IRB. The deadline for submission to the IRB is three weeks in advance of the meeting, and is noted within the IRB meeting schedule provided to investigators and IRB members. Formal protocol submission requirements for investigators are addressed in separate SOPs (WRAIR SOP UWZ-C-603, Conducting Initial Review of Human Subjects Research, and WRAIR SOP UWZ-C-623, Submission of Human Subjects Research Protocols and Supporting Documents for Review). Once provided, documents are posted on a secure website for DHSP and IRB member access only.



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d. Selection of Primary and Secondary Reviewers

- 1) The WRAIR IRB applies the Primary Reviewer System. This type of review system allows for two IRB members (referred to as the primary reviewer and secondary reviewer) to be assigned to each of the following agenda items: new protocols, continuing reviews, major amendments and other submissions deemed appropriate by the IRB Chair and IRB Administrative Director. Utilization of both a primary and secondary reviewer for each item may not be necessary, and additional reviewers may be assigned, as appropriate. Although certain members will be assigned to specific protocols, all IRB members are responsible for reviewing all items included in the IRB packet.
- 2) Reviewers are assigned by the IRB Administrative Director or designee in consultation with the WRAIR IRB Chair and DHSP staff.
- 3) Requests for IRB members to serve as primary and/or secondary reviewers are generally sent at least 7 days prior to the meeting.
- 4) During the IRB meeting, the primary reviewer presents a summary of the protocol and any potential issues or concerns. If assigned, a secondary reviewer may or may not have additional comments. All items will be reviewed in accordance with 32 CFR 219.111 and other applicable regulations, laws and policies.

e. Membership and Quorum

- 1) A quorum consists of half the regular voting members listed on the WRAIR IRB roster plus one and must include at least one member whose primary concerns are in non-scientific areas (i.e. non-scientist). An alternate may substitute for a single regular member and may vote.
- 2) To contribute towards a quorum, members must be present in person or by telephone; if a member cannot be present he/she can provide written input, but cannot vote or be counted as part of the quorum.
- 3) There must be at least five members on the IRB roster at any given time. One of these must be a non-scientist and one must be unaffiliated.
- 4) Recused members do not count towards the quorum.



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f. Teleconferencing

- 1) Teleconferencing is defined as a meeting with members at remote sites participating via an audio connection. Video teleconferencing is defined as a meeting with members at remote sites using a video and audio connection.
- 2) IRB meetings may be held by teleconference, as permitted by the Office for Human Research Protections (OHRP) of the United States Department of Health and Human Services. Should the WRAIR IRB decide to hold a teleconference, the meeting minutes reflect that regular meeting requirements have been met.

g. *Ad hoc* and Sub-committee IRB Meetings

- 1) Under special circumstances, the IRB Administrative Director can schedule an *ad hoc* IRB meeting. This can be done via teleconference as defined above. *Ad hoc* meetings for emergency situations meet all regular meeting requirements.
- 2) Under special circumstances, the IRB Chair can request that a sub-committee meeting be held. Sub-committee meetings can be requested by a fully convened IRB or the IRB Chair and do not require a quorum, however, no voting will occur during the sub-committee. The discussion and/or recommendations from the sub-committee meeting will be made available to the full IRB for voting.

h. Absence of Chair

The Vice Chair may preside over convened meetings in which the Chair is not present. If neither the Chair nor the Vice Chair is present at a regularly scheduled meeting, an experienced member of the WRAIR IRB may be temporarily appointed as "Acting Chair" by the IRB Chair.

i. Conflict of Interest

No IRB member may participate in deliberations or voting on any protocol in which he/she has a conflicting interest and must recuse him/herself, except to provide information to the IRB when requested. In this case, if the IRB member is an investigator, he/she will be required to fill out a Conflict of Interest Disclosure Form, as well (Refer to WRAIR SOP UWZ-C-609, Identification and Management of Conflicts of Interest,).



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j. Investigators/IRB Members

During the meeting, investigators may be invited to offer information to the IRB; however, they are not to be present for closed discussion or the vote (even if this means the meeting will be unable to continue due to quorum requirements). Voting is to be confidential, and should not be discussed outside of the meeting with Investigators or others.

k. Guests

Those individuals who attend the WRAIR IRB Meeting, who are not WRAIR IRB Members, document their attendance by signing the WRAIR IRB Sign-in sheet (Appendix A) and the WRAIR IRB Non Disclosure Form (Appendix B), as appropriate.

k. Meeting minutes:

The IRB meeting minutes are written in sufficient detail to include the following: attendance, quorum, expedited review list, discussion summary and voting (Refer to WRAIR SOP UWZ-C-625, WRAIR IRB Meeting Minutes).



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**5. Explanation of Abbreviations and Terms:**

COI	Conflict of Interest: 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.
CONUS	Continental United States
DHSP	Division of Human Subjects Protection, WRAIR, is the administrative branch of the WRAIR IRB.
IRB	An Institutional Review Board or ethical review committee that reviews research involving human subjects, as per the cited regulations and policies.
Motion	A formal proposal put to the vote after being seconded.
Packets	Meeting Materials submitted to the WRAIR IRB for review
Primary Reviewer System	The WRAIR IRB applies this type of review system which includes two committee members taking responsibility for a detailed review of a research study. At the time of the IRB meeting, the primary and secondary reviewers provide comments and recommendations to the full committee.
Quorum	The minimum number of members of the IRB who must be present for a valid motion to pass. This is defined as one more than half the members (including pre-determined alternates) listed on the current roster. A non-scientist must be among those present.
Recuse	An IRB member that has a conflict of interest or other issue pertaining to the review and approval of a protocol should dismiss himself/herself from the meeting room during the closed discussion and vote, at the discretion of the Chair or Acting Chair. Recused members do not contribute towards the quorum.
Research	Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.



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Teleconference A meeting with members at remote sites via an audio connection.

WRAIR Walter Reed Army Institute of Research

WRAIR Institutional Review Board (IRB) The ethical review committee for research involving human subjects 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.



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## 6. References

Reference Number or Authors	Document Title
AR-40-68	<i>Clinical Quality Management</i> , 26 February 2004.
AR-70-25	<i>Use of Volunteers as Subjects of Research</i> , 25 January 1990
WRAIR IRB Charter	Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Charter.
ICH-GCP-E6	<i>Guideline for Good Clinical Practice</i> .
OHRP Guidelines	<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>
Titles 21, 32 and 45	<i>Code of Federal Regulations</i>
WRAIR HRPP	<i>WRAIR Human Research Protection Program (HRPP)</i>
Amdur, R. J. and Bankert, E. A.	<i>Institutional Review Board Management and Function</i> (2 <sup>nd</sup> Edition). Boston: Jones and Bartlett Publishers, 2006.
WRAIR SOP UWZ-C-603	Conducting Initial and Protocol Review
WRAIR SOP UWZ-C-609	Identification and Management of Conflicts of Interest
WRAIR SOP UWZ-C-623	Submission of Protocols and Informed Consent Forms
WRAIR SOP UWZ-C-625	WRAIR IRB Meeting Minutes



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**7. Forms and Appendices:**

Form or Appendix Number	Title
Form A	WRAIR IRB Sign In Sheet
Form B	WRAIR IRB Non Disclosure Form

**8. Document Revision History**

Version Number	Brief Description of Changes	Effective Date
.00	New	10 February 2007
.01	Biennial review, update organization name changes and provide clarifications regarding procedures and definitions	08 April 2009
0.2	Biennial review. Updates to current processes and references to policies/procedures.	MAR 2 1 2011

IRB Guests  
Sign-in  
**Date of Meeting**  
WRAIR IRB Meeting  
*(IRB Members do **not** need to sign)*

	Name (print)	Signature	Division/Association
1			
2			
3			
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**Walter Reed Army Institute of Research (WRAIR), Institutional Review Board (IRB)**

Date of Meeting: \_\_\_\_\_

**Guests of the WRAIR IRB**

Guests of the WRAIR IRB hereby agree not to use the Confidential Information disclosed in today's meeting in any way, or to manufacture or test any product embodying Confidential Information.

No Disclosure. Guests of the WRAIR IRB agree to use their best efforts to prevent and protect the Confidential Information, or any part thereof, from disclosure to any person other than Recipient's employees having a need for disclosure in connection with Recipient's authorized use of the Confidential Information.

DISCLOSER representing the WRAIR  
IRB

Signed:

\_\_\_\_\_

Print Name: \_\_\_\_\_

Title: Administrative Director, WRAIR  
IRB

Date: \_\_\_\_\_

Guest RECIPIENT of the WRAIR IRB

Signed:

\_\_\_\_\_

Print Name:

\_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_