



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

SOP Title	<b>INSTITUTIONAL REVIEW BOARD VOTING REQUIREMENTS</b>	SOP No.	<b>UWZ-C-610</b>
		Version	<b>.02</b>
Effective Date	<i>APR 06 2011</i>	Page	1 of 8

**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) outlines the process used by the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) to document voting by members of the IRB. Decisions at fully convened IRB meetings are made by a vote of a quorum of the duly constituted IRB. This SOP applies to the WRAIR Division of Human Subjects Protection (DHSP) Staff, the WRAIR IRB Administrative Director, the WRAIR IRB Chair, and WRAIR IRB Members.
- 2. Responsibilities:** Those taking responsibility for the actions in the SOP are the IRB members, the IRB Administrative Director, and the DHSP staff.
  - a. The IRB members are responsible for:
    - 1) Taking appropriate action regarding any Conflicts of Interest (COI), abstentions or recusals, and
    - 2) Voting according to these procedures.
  - b. The IRB Administrative Director is responsible for:
    - 1) Ensuring the convened meeting consists of a quorum, and
    - 2) Ensuring the IRB members vote according to these procedures.
  - c. The DHSP Staff is responsible for:
    - 1) Ensuring that votes are recorded according to these procedures, and
    - 2) Ensuring voting sheets are destroyed upon finalization of the IRB meeting minutes.
- 3. Materials and Equipment:** Not Applicable.
- 4. Procedures:**
  - a. A convened meeting consists of a quorum, which is comprised of a majority of the members of the IRB, including at least one scientist and one non-scientist. It is preferable to also have a non-affiliated member present, but is not required.
  - b. In order for proposed research requiring review by a fully convened IRB to be approved, it must receive the approval of a majority of those members present at the meeting. The voting quorum is by a verbally stated vote or hand-raising



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and is recorded into the IRB minutes. Voting sheets may be utilized, but are not required (see Form A). If voting sheets are used, they must be destroyed upon finalization of the IRB meeting minutes (see SOP UWZ-C-625, IRB Meeting Minutes).

- c. All members voting on a protocol must be free of conflicts of interest with respect to the biologic, drug, device or other relationship(s) to the study, investigator, or Sponsor involved (refer to WRAIR SOP UWZ-C-609, Identification and Management of Conflicts of Interest). Any member with a conflicting interest recuses himself/herself from voting on the protocol and this conflict is documented in the IRB Minutes. Noted recusals are not counted towards the quorum.
- d. A member of the IRB may also abstain or recuse himself/herself from voting on an agenda item for personal/other reasons. The member is asked to state his or her reason for abstention/recusal. Unlike a recusal, an abstention is counted as a vote towards the quorum. .
- e. Only regular members (or their alternates) listed on the current IRB roster and who are in attendance may vote (teleconference votes are permitted). Consultants, observers, and members of the administration may not vote, but may be present for discussion, if deemed appropriate by the full IRB. Investigators may not be present during closed discussion and vote.
- f. No vote by proxy is permitted.
- g. A vote is called once discussion is completed. One member proposes a motion and another member must second the motion. If a second to a motion is not provided, the motion is not carried, and an alternate motion must be posed. Approval of a motion must be made by a majority vote of those members present during the vote. If the motion does not pass by a majority vote, an alternate motion must be proposed.
- h. The WRAIR IRB Chair/Acting Chair is counted in the quorum and votes, unless he/she recuses himself/herself due to a conflict of interest, or requests to abstain. As noted above, rationale for abstentions/recusals by the Chair/Acting Chair will be documented in the meeting minutes.



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- i. The vote to pass or reject motions on all WRAIR IRB actions is documented in the IRB meeting minutes. The minutes include the number of members voting for, against, abstaining and recusing.
- j. While it is not required to call for a vote to ratify protocols approved by expedited review, any IRB member may request a full IRB review and vote on any protocol or action approved via expedited review by making a formal written (email, fax, or memo) request with justification to the IRB Administrative Director or the WRAIR IRB Chair. If considered justified by the IRB Administrative Director or the IRB Chair, the request is brought to the full IRB for further discussion and a final decision.



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

Abstain	An IRB member who does not have a conflict of interest, but otherwise feels unable to vote (e.g., left the room during the discussion, does not understand the subject matter, or did not read the protocol and supporting documents in advance of the meeting) may abstain from voting. Abstaining members contribute towards the quorum.
COI	Conflict of Interest
DHSP	Division of Human Subjects Protection, WRAIR, provides administrative support for the IRB
Human Subjects Research	Research involving humans as research subjects, or involving data, 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.
IRB	(IRB) An ethical review committee that reviews research involving human subjects, as per the cited regulations and policies.
Motion	A formal proposal put to a vote.
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 scientist and 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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SOP

Standard Operating Procedures

WRAIR

Walter Reed Army Institute of Research

WRAIR Institutional Review Board (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 (e.g. investigator). This includes protocols for which recruitment of subjects is being performed at WRAIR.



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**6. References:**

Reference Number or Authors	Document Title
Titles 21, 32 and 45	<i>Code of Federal Regulations</i>
ICH-GCP-E6	<i>Guideline for Good Clinical Practice.</i>
OHRP Guidelines	<i>Guidance on Written IRB Procedures, 15 January 2007.</i> <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm">http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm</a>
AR-40-68	<i>Clinical Quality Management</i>
AR-70-25	<i>Use of Volunteers as Subjects of Research</i>
WRAIR IRB Charter	Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Charter.
WRAIR HRPP	<i>WRAIR Human Research Protection Program (HRPP)</i>
Amdur, R. J. and Bankert, E. A.	Institutional Review Board Management and Function (2 <sup>nd</sup> Edition). Boston: Jones and Bartlett Publishers, 2006.
WRAIR SOP UWZ-C-609	Identification and Management of Conflicts of Interest
WRAIR SOP UWZ-C-625	WRAIR IRB Meeting Minutes

**7. Forms and Appendices:**

Form or Appendix Number	Title
Form A	Voting Sheet Template



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**8. Document Revision History:**

Version Number	Brief Description of Changes	Effective Date
.00	New SOP	2 Jan 07
.01	Biennial review, update organization name changes and provide clarifications regarding procedures and definitions	2 Feb 09
.02	Biennial review, updates regarding current processes, procedures, and addition of a form.	<i>APR 06 2011</i>

This meeting is being recorded. The recording will be erased once the Meeting Minutes are finalized.

Member: \_\_\_\_\_

Arrival Time: \_\_\_\_\_  
 (if after start of meeting)

Signature: \_\_\_\_\_

Departure Time: \_\_\_\_\_  
 (if prior to the end of meeting)

WRAR IRB Meeting									
A) New Protocols									
WRAR #: "TITLE" (VERSION #, DATE), submitted by INVESTIGATOR NAME, CREDENTIALS, TITLE, DEPARTMENT, DIVISION, INSTITUTION Primary Reviewer: NAME, CREDENTIALS Secondary Reviewer: NAME, CREDENTIALS									
B) Continuing Review Report									
WRAR #: "TITLE" (VERSION #, DATE), submitted by INVESTIGATOR NAME, CREDENTIALS, TITLE, DEPARTMENT, DIVISION, INSTITUTION Primary Reviewer: NAME, CREDENTIALS Secondary Reviewer: NAME, CREDENTIALS									
C) Amendment									
WRAR #: "TITLE" (VERSION #, DATE), submitted by INVESTIGATOR NAME, CREDENTIALS, TITLE, DEPARTMENT, DIVISION, INSTITUTION Primary Reviewer: NAME, CREDENTIALS Secondary Reviewer: NAME, CREDENTIALS									

COI: Conflict of Interest

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