Standard Operating Procedure
Walter Reed Army Institute of Research

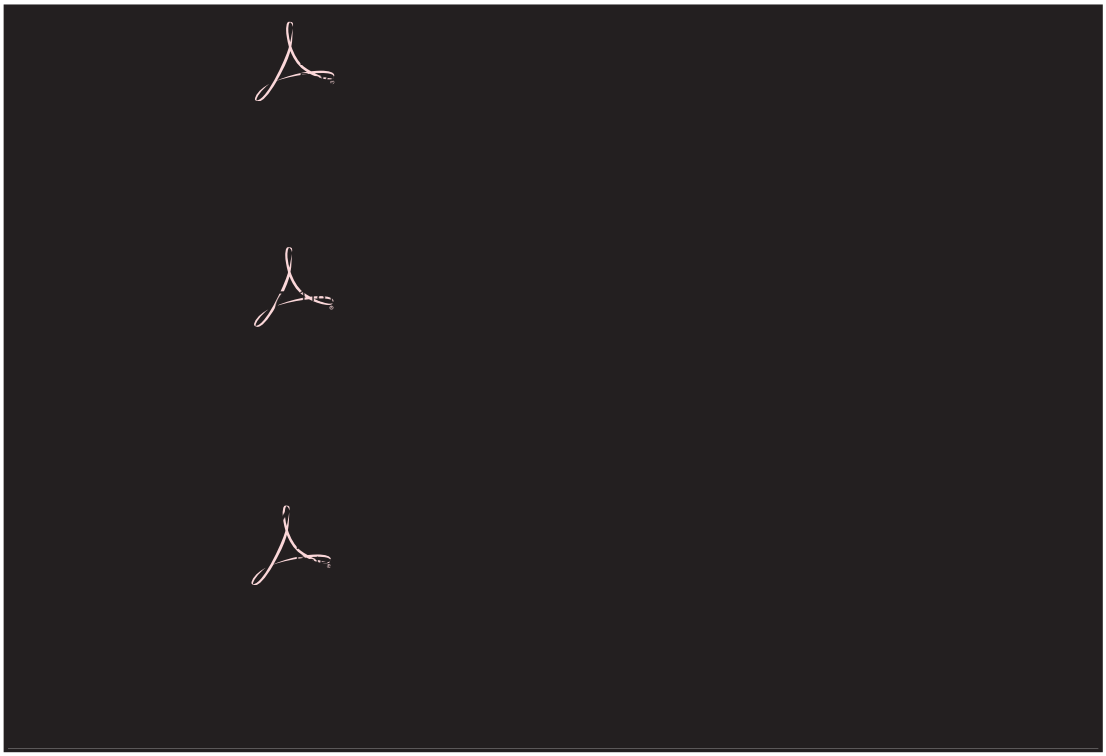
SOP:	**INSTITUTIONAL REVIEW BOARD MEETINGS and VOTING REQUIREMENTS**	**SOP No.:**	UWS-HP-610
		Version:	.05
Effective Date:	07 August 2024	**Page:**	1 of 12

Signatures and Dates:

Author:

QA Review:

Approving Authority:



Review/Approval for unchanged documents

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1. Purpose and Applicability

This Standard Operating Procedure (SOP) outlines the process used by the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) to conduct meetings and 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 IRB Chair, WRAIR IRB Members, the WRAIR IRB Administrative Director, the WRAIR IRB Coordinator, and WRAIR Human Subjects Protection Branch (HSPB) Staff.

2. Roles & Responsibilities

a. The IRB members are responsible for:

1) Notifying the IRB Coordinator or the IRB Administrative Director (or his/her designee) or other point of contact of their availability to attend the meeting.

2) Taking appropriate action regarding any Conflicts of Interest (COI), abstentions or recusals, in accordance with the WRAIR SOP UWS-HP-609, Identification and Management of Conflict of Interests.

3) Voting according to these procedures.

b. The IRB Administrative Director is responsible for:

1) Ensuring the convened meeting consists of a quorum.

2) Ensuring the IRB members vote according to these procedures.

c. The WRAIR IRB Coordinator and HSPB Staff are responsible for:

1) Preparing a schedule of meetings and the respective submission due dates for the following calendar year.

2) Distributing the schedule to IRB members and WRAIR Investigators, as well as posting the schedule on the WRAIR website.

3) Reserving the meeting room and the bridge-line, and the virtual video teleconferencing link through the calendars in Microsoft (MS) Outlook Calendar.

4) Arranging pre-IRB meetings with the IRB Chair or Acting Chair.

5) Notifying selected primary and secondary reviewers after the pre-IRB meeting, but not less than one (1) week before the scheduled IRB meeting.

6) Ensuring each IRB member receives all pertinent review materials at least one (1) week prior to the meeting. The meeting documents will be provided to the WRAIR IRB members through the Department of Defense (DoD) Secure Access File Exchange (SAFE) website. Other means of securely sending materials may be used, if necessary.

7) Securing from guests all WRAIR IRB Non-Disclosure Forms (Form A) prior to the WRAIR IRB meeting.

8) After the meeting is complete, making one copy of the meeting recording on the relevant meeting platform.

9) Preparing meeting minutes in accordance with the WRAIR SOP UWS-HP628, Review of Human Subjects Research by the Fully Convened WRAIR IRB.

10) Ensuring that votes are recorded in the meeting minutes according to these procedures.

11) Ensuring the meeting recording is destroyed upon finalization of the IRB meeting minutes.

3. Materials and Equipment

Not Applicable

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) Pre-IRB Meetings are generally scheduled the day following the protocol submission deadline (approximately three (3) weeks prior to the WRAIR IRB meeting).

2) WRAIR IRB Meetings are held monthly, usually on the second Wednesday of each month at 0900 hours

3) WRAIR IRB Meetings are held in Building 503, WRAIR and/or over a virtual teleconferencing link.

4) WRAIR IRB Meetings require a quorum and a non-scientist for a meeting to convene (refer to section 4e of this SOP for membership and quorum details).

b. Meeting Agenda

1) The agenda may include but is not limited to the following items: minutes from previous meetings, new protocols, continuing reviews, amendments, deviation reports, serious adverse event reports, UPIRTSOs, 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 seven (7) days prior to the meeting date. All IRB members have access to electronic copies via the DoD SAFE (or alternate) website.

c. Protocols/Items for review

1) It is expected that protocols for review be in final form, when appropriate, incorporating changes requested from the HSPB pre-review, and have obtained scientific approval prior to submission to the IRB.

2) The deadline for submission to the IRB is three (3) 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 (see WRAIR SOP UWSHP-603, Conducting Initial Review of Human Subjects Research, and WRAIR SOP UWS-HP-623, Submission of Human Subjects Research Protocols and Supporting Documents for Review). Once provided, documents are posted on a secure website for HSPB and IRB member access only.

d. Selection of Primary and Secondary Reviewers

1) The WRAIR IRB applies the Primary Reviewer System. This type of review system allows for two (2) 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, 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 HSPB staff.

3) Requests for IRB members to serve as primary and/or secondary reviewers are generally sent after the WRAIR pre-IRB meeting, but not less than seven (7) days prior to the meeting.

e. Membership and Quorum

1) A quorum consists of half the regular voting members listed on the WRAIR IRB roster plus one (1) and must include at least one (1) 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, via a video teleconferencing link, 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 (5) members on the IRB roster at any given time. One (1) of these must be a non-scientist and one (1) must be unaffiliated.

4) Recused members do not count towards the quorum, however, members who abstain from particular voting items count towards the quorum.

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. When the WRAIR IRB decides to hold a teleconference, the meeting minutes will reflect that regular meeting requirements have been met.

3) Bridge-line information (phone number, bridge-line number, and passcode) and/or a video teleconferencing link will be provided to all IRB members prior to the meeting for IRB members who are unable to attend in person.

g. *Ad hoc* 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 must meet all regular meeting requirements.

2) In certain instances, 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 meeting. The discussion and/or recommendations from the sub-committee meeting will be made available to the full IRB for voting or for information.

h. Absence of Chair

The Vice Chair may preside over convened meetings in which the Chair is not present or has declared a conflict of interest. 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 or Vice 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 (see WRAIR SOP UWS-HP609, Identification and Management of Conflicts of Interest).

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, sign the WRAIR IRB Non-Disclosure Form (Form A), as appropriate. The IRB Coordinator documents all attendees by verbally naming them for the audio recording.

l. Subject Matter Expert (SME)

Subject Matter Experts may be invited to attend a specific IRB meeting to provide knowledge on protocol specific topics and address specific questions and concerns raised by the IRB members. The SMEs attendance will be documented by asking him/her to sign a Non-Disclosure Form, as appropriate.

m. Voting Requirements

1) A quorum and a non-scientist IRB member must be present for a meeting to convene. It is preferable to also have a non-affiliated member present, but is not required.

2) 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 and is recorded into the IRB minutes.

3) All members voting on a protocol must be free of conflicts of interest with respect to the biologic, drug, device, combination product or other relationship(s) to the study, investigator, or Sponsor involved (see WRAIR SOP UWS-HP-609, Identification and Management of Conflicts of Interest). Any member with a conflicting interest must recuse himself/herself from voting on the protocol and this conflict is documented in the IRB Minutes. Noted recusals are not counted towards the quorum. It is not necessary to provide a reason unless the IRB member wants the board to make a decision in order for them to be allowed to vote. If the IRB member chooses to provide a reason so that they can vote and the IRB agrees there is no COI, then the IRB member may vote and be counted in the quorum.

4) A member of the IRB may also abstain from voting on an agenda item for personal/other reasons. The member is asked to state his or her reason for abstention. Unlike a recusal, an abstention is counted as a vote towards the quorum.

5) 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.

6) No vote by proxy is permitted.

7) A vote is called once discussion is completed. One (1) member, usually the primary reviewer, 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.

8) 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.

9) 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, or recusing.

10) Approvals with stipulations, unless specifically stated within the motion for approval, will be remanded to the IRB Chair or Designee(s) for review. Documentation that stipulations have been adequately addressed will be included in the IRB approval memorandum.

11) 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.

n. Meeting Minutes

The IRB meeting minutes are written in sufficient detail to include the following: attendance, quorum, expedited review list, discussion summary and motion(s) (see WRAIR SOP UWS-HP-628, Review of Human Subjects Research by the Fully Convened WRAIR IRB).

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

Note: Abbreviations and acronyms have been defined in the text at the time of first use.

7. References

Reference Number or Author	Document Title
21 Code of Federal Regulations (CFR) 56	U.S. Food and Drug Administration, Institutional Review Boards
32 CFR 219	Department of Defense, Protection of Human Subjects
45 CFR 46	Health and Human Services, Protection of Human Subjects
ICH-GCP-E6	Guideline for Good Clinical Practice
OHRP Guidelines	IRB Written Procedures: Guidance for Institutions and IRBs (2018)
AR 40-68	Clinical Quality Management

WRAIR IRB Charter	Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Charter
WRAIR HRPP	WRAIR Human Research Protection Program (HRPP)
Amdur, R. J. and Bankert, E. A.	Institutional Review Board Member Handbook (3rd Edition), Boston: Jones and Bartlett Publishers, 2021
WRAIR SOP UWS-HP-603	Conducting Initial Review of Human Subjects Research
WRAIR SOP UWS-HP-609	Identification and Management of Conflicts of Interest
WRAIR SOP UWS-HP-623	Submission of Human Subjects Research Protocols and Supporting Documents for Review
WRAIR SOP UWS-HP-628	Review of Human Subjects Research by the Fully Convened WRAIR IRB

8. Appendices and Attachments

Appendix or Attachment Number	Title
Form A	WRAIR IRB Non-Disclosure Form

9. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	New SOP	02 Jan 2007
.01	Biennial review, update organization name changes and provide clarification regarding procedures and definitions.	02 Feb 2009

.02	Biennial review, updates regarding processes, procedures and addition of a form.	06 April 2011
.03	Review and revisions to combine with SOP UWZ-C-616, incorporate updated guidance, policies and regulations, and minor editorial clarifications.	30 January 2020
.04	Removal of definitions, webpage link to OHRP Guidelines, and appendices A and C. Updates procedures due to remote meeting attendance.	24 August 2022
.05	Reformatted using new WRAIR SOP template and other minor administrative and editorial changes.	07 August 2024

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	Guest RECIPIENT of the WRAIR IRB
Signed: _____	Signed: _____
Print Name: _____	Print Name: _____
Title: Administrative Director, WRAIR IRB	Title: _____
Date: _____	Date: _____