SOP Title	**REVIEW OF HUMAN SUBJECTS RESEARCH BY THE FULLY CONVENED WRAIR INSTITUTIONAL REVIEW BOARD**	SOP No.	UWS-HP-628
		Version	.02
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Signatures and Dates:

Author: [redacted]

QA Review:

Approving Authority:

Review/Approval for unchanged documents

	Author/Date	QA Review/Date	Approving Authority/Date
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1. Purpose and Applicability

This Standard Operating Procedure (SOP) describes the process the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) members use to review human subjects research protocols at fully convened IRB meetings and the process used to prepare, distribute and maintain official copies of the meeting minutes. The procedure outlined in this SOP applies to initial protocol submissions and life cycle actions (amendments, continuing review reports, safety reports, protocol deviations, etc.). This SOP also aims to ensure that the IRB meeting minutes are in compliance with applicable federal, Department of Defense (DoD) and Department of the Army/Defense regulatory requirements. For the purpose of this SOP, “protocol submission” means the complete study documentation to include the protocol, consent document, and applicable supporting material (see WRAIR Policy #24, Submission of Protocols Involving Human Subjects, Human Information or Biospecimens, for Scientific and Ethical Review, and SOP UWS-HP-623, Submission of Human Subjects Research Protocols and Supporting Documents for Review, Appendix A, *Required Documents for Submission Checklist*). This SOP also provides criteria to use when reviewing protocols.

This SOP applies to the Human Subjects Protection Branch (HSPB) Staff, the WRAIR IRB Coordinator, WRAIR IRB members, the WRAIR IRB Chair, the WRAIR IRB Administrative Director and the WRAIR Commander (Institutional Official; IO).

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 WRAIR 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, provide comments, and lend to the discussion.

2. Responsibilities

a. WRAIR HSPB staff members are responsible for:

1) Determining that a packet is complete and all the required elements (as specified in SOP UWS-HP-623 and WRAIR Submission Policy) 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 review via expedited review procedures.

2) Assisting with developing the agenda for IRB meetings and assignment of primary and secondary reviewers. This will include identifying applicable regulations and potential conflicts of interest and drafting context to be included in the agenda.

3) Facilitating communications between the PI, WRAIR POC or study staff and IRB members, in order to address any questions in advance of the meeting.

4) Attending the fully convened IRB Meeting for the duration of the review and discussion for agenda items.

5) Preparing, editing and finalizing the communication to the PI and IRB meeting minutes.

b. The WRAIR IRB Coordinator is responsible for:

1) Preparing the IRB meeting agenda and minutes template.

2) Providing the agenda to IRB Administrative Director or designee for review and signature prior to the dissemination of documents to the IRB.

3) Providing the drafted meeting minutes to WRAIR IRB Administrative Director/designee for minute's review within ten business days following an IRB meeting.

4) Providing the finalized version of the minutes to WRAIR IRB members.

5) Ensuring finalized minutes are properly distributed, stored, and maintained.

6) Sending a copy of the finalized minutes to the United States Army Medical and Development Command (USAMRDC), when requested.

c. WRAIR IRB members are responsible for:

1) Reviewing each action item on the WRAIR IRB meeting agenda ahead of the WRAIR IRB Meeting or WRAIR IRB Subcommittee meeting.

2) Communicating with the PI, WRAIR POC and HSPB protocol POC to address any questions in advance of the meeting.

3) Being prepared to discuss and raise any concerns regarding agenda items at full board and subcommittee meetings.

4) Serving as primary or secondary reviewers, which requires presenting a summary of the study and any items or issues that may need to be addressed.

5) Presenting a motion at the IRB meeting.

6) Reviewing final versions of minutes from previous meetings and offering edits/comments back to the HSPB.

7) Reviewing the cumulative list of items reviewed via expedited procedures for the previous month.

Note: No vote for the review of prior minutes or expedited actions is recorded; instead these items are identified in the record as having been reviewed.

d. WRAIR IRB Chair or Designee, in addition to part c, is also responsible for:

1) Assigning primary and secondary reviewers (in coordination with the IRB Administrative Director and HSPB Staff).

2) Determining that a packet is complete and ready for review by the WRAIR IRB, by either the full board or expedited review process.

3) For protocol submissions, reviewing minor changes requested by the WRAIR IRB and remanded to the WRAIR IRB Chair or Designee, reviewing life cycle actions that qualify for review via expedited review procedures, and reviewing and approving protocol submissions specified in SOP UWS-HP-613.

4) Reviewing and signing the final version of the IRB meeting minutes.

e. WRAIR IRB Administrative Director or Designee is responsible for:

1) Assigning primary and secondary reviewers (in coordination with the IRB Chair).

2) Reviewing and signing the IRB meeting agenda.

3) Attending the fully convened IRB Meeting.

4) Reviewing and signing the final version of the IRB meeting minutes.

f. WRAIR Commander/Institutional Official is responsible for reviewing and signing the final version of the IRB meeting minutes.

3. Investigator Guidance

a. In order for a protocol to be considered for review during one of the listed IRB Meeting dates, the following criteria must be met by the corresponding submission deadline:

1) qualify as a complete submission in accordance with WRAIR SOP UWS-HP 623 and WRAIR Policy #24;

2) scientific review approval has been received by the HSPB; and

3) all comments (unless minor and waived by the Director, HSPB or IRB Chair) in the Protocol Evaluations Form (PEF) have been adequately addressed by the study team and accepted by the HSPB.

The submission deadlines for IRB Meetings are provided on a Calendar year basis and are available on the WRAIR website or can be provided by HSPB personnel upon request.

b. The PI or WRAIR POC is expected to answer questions from the HSPB, WRAIR IRB, USAMRDC Office of Human and Animal Research Oversight (OHARO), the Army Human Research Protection Office (AHRPO), and IRB members, as applicable, regarding the protocol or protocol life cycle submission.

c. Attend (via phone or in-person), if requested, the WRAIR IRB meeting at which the protocol or life cycle action is reviewed, to discuss any important issues that could not be resolved before the meeting.

4. Procedures

a. HSPB staff is expected to:

1) Determine if the submission of the protocol or life cycle action is complete (per the SOP UWS-HP-623 and WRAIR Policy #24) and contains the required elements (as specified in SOP UWS-HP-603) and is submitted to the WRAIR HSPB by the submission deadline.

   Note: Protocols or life cycle action submissions that are reviewed and determined to not be complete by the submission deadline may only proceed for IRB review if permission is granted by both, the HSPB Administrative Director or Designee and the IRB Chair or IRB Chair designee.

2) Provide the WRAIR IRB Coordinator with protocol number, protocol title, versions and version dates, and brief context of the item to be included in the agenda.

3) Assist the WRAIR IRB Chair with assignment of primary and secondary reviewers (based on expertise, availability, prior reviewers, conflicts of interest, as well as other considerations).

4) Organize protocol and supporting documents in a manner to facilitate review process by IRB Members.

5) Facilitate communication between the PI and/or WRAIR POC, as well as the WRAIR IRB members, to answer questions and/or obtain additional information, if needed, prior to the fully convened IRB meeting. Controversial issues should be resolved through the HSPB Director and IRB Chair or IRB Chair Designee prior to the WRAIR IRB Meeting, as appropriate.

6) Attend the fully convened meeting.

7) Prepare, edit and finalize the discussion of agenda items, as follows:

   a. HSPB staff will prepare the discussion portions of the meeting minutes write up. The discussion is comprised of pertinent background or contextual information presented at the meeting, summary of the discussion by members and guests, highlights of member concerns and areas for improvement.

   b. Once the discussion is drafted by the HSPB staff, it should be provided to the IRB Coordinator.

Note: The meeting minutes discussions are generally drafted, and sent to the IRB Coordinator within 5 working days of the IRB meeting.

8) Prepare, edit and finalize the communication to the PI, as follows:

a. HSPB staff will prepare the "IRB Communication to PI" (referred to as the communication). The communication is comprised of the title of the protocol reviewed, action taken by the Board, summary of any controverted issues, and any stipulations. (See Appendix E)

Note: If an action is submitted for information only, or is approved as submitted (e.g., without stipulations), a communication is not required.

b. Once the communication is drafted by the HSPB staff, it is reviewed by the following personnel in the order as seen below:

i. IRB Administrative Director and/or HSPB Deputy Director for comment/edits. Noted changes are incorporated into the communication by the HSPB staff.

ii. IRB Chair/Acting Chair, Primary/Secondary reviewers, and any member who provided significant contribution during the discussion. Noted changes are incorporated into the communication by the HSPB staff.

c. HSPB staff then sends the final version of the communication to the PI and/or WRAIR POC, IRB Coordinator, IRB Chair, and any additional applicable parties.

Note: The communication is generally drafted, reviewed and sent to the PI and/or WRAIR POC within 5 working days of the IRB meeting.

d. The IRB Coordinator combines the discussions and communications, and finalizes the meeting minutes using the minutes template.(See Appendix E)

9) Together with the IRB Coordinator, prepare the IRB Meeting Minutes to include the following as content:

a) The time period of the actual meeting, as well as the separate deliberations, actions, and votes for each protocol or life cycle action reviewed/discussed by the convened WRAIR IRB. The context reviewed during an IRB meeting is initially reflected in the WRAIR IRB agenda that is sent to IRB members in the read-ahead packet. (Reference Appendices D and E)

b) In accordance with the Common Rule (32 CFR 219.115), the WRAIR IRB meeting minutes must include the following:

i. Attendance at the meetings. A quorum, to include the presence of at least one non-scientist throughout the meeting shall be stated and maintained during the course of the meeting. The list of attendees should also include the names of all non-member persons attending any part of the IRB meeting and may list them as guests, as appropriate.
ii. Actions/motions taken by the WRAIR IRB. This may include, but is not limited, to approval, approval with stipulations, tabling and disapproval.
iii. Vote on these actions/motions, including the number of members voting for, against, abstentions, and recusals. (Reference IRB Meetings and Voting Requirements SOP UWS-HP-610)
iv. The basis for approval or requirement of changes, require modifications (also termed “table” or “deferral”) or disapprovals of research.
v. Written summary of the controverted issues and their resolution.

c) Special required considerations, citing the applicable regulations:

i. Approving research with waiver of informed consent.
ii. Approving research with waiver of the documentation of informed consent.
iii. Approving research involving pregnant women. (Subpart B)
iv. Approving research involving prisoners. (Subpart C)
v. Approving research involving children. (Subpart D)
vi. Other (e.g., 10 USC 980, applicable U.S. Food and Drug Administration [FDA] regulations, etc.)

d) The risk level determined by the IRB for new, revised, or continuing protocols approved by the convened WRAIR IRB.

e) The period of approval for initial review and continuing review of protocols. The standard period of approval is 12 months. If the IRB recommends a protocol approval period of less than 12 months, include the justification for the shorter term of approval and any requirements to be fulfilled by the investigator by the end of this term.

f) Separate deliberations, actions, and votes for each amendment or sub-study added to a protocol, including any changes to the informed consent arising from such submissions. Document when the WRAIR IRB determines that an amendment or sub-study changes the risk level of the protocol, as well as any change in the approval period.

g) Separate deliberations, actions, and votes for each report of unanticipated problems, protocol deviations, adverse events (AEs), and serious or continuing noncompliance. The minutes shall include the determination of relatedness to the use of the study product (drug or device) or procedure. (References: Safety Reporting for Clinical Trials SOP UWS-HP-619; Deviation and Unanticipated Problem Reporting SOP UWS-HP-621; and Non Compliance Procedures SOP UWS-HP-606)

h) The amount of time (typically 30 days, 60 days or 6 months) the PI or WRAIR POC has to respond to any stipulations to approval. If stipulations are dictated, but no time specified, the default is 30 days.

i) Disclose in the opening section of the meeting minutes any conflicts of interest and the circumstances in which members present for the meeting with conflicts of interest do not participate in the deliberations or voting. (Reference: Safety Reporting for Clinical Trials SOP UWS-HP-609, Identification and Management of Conflicts of Interest)

j) Document in the minutes the following, if applicable:

   i. IRB continuing education materials that are distributed.
   ii. Reports from IRB sub-committees.
   iii. Discussion of IRB administrative policies and procedures, including SOPs and training on such.

iv. Results of any IRB compliance visits or investigation (routine post approval compliance monitoring, report of noncompliance, identified conflicts of interest, complaints, etc.).
v. Summary of expedited review actions taken by the WRAIR IRB Chair or Designee and any additional related discussions.
vi. Other review items or information only items, as determined by the WRAIR IRB Administrative Director or WRAIR IRB Chair or his/her Designee.

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.

2) Serve as primary and secondary reviewers for protocol submissions. Promptly notify the HSPB if they cannot fulfill their duties as assigned.

3) Provide written comments to the HSPB staff following the conclusion of the WRAIR IRB meeting, as appropriate.

4) Review the draft version of the communication to the PI prepared by HSPB staff and provide comment/edits.

c. Primary and secondary WRAIR IRB reviewers are expected to:

1) Conduct a thorough review of the protocol by using the following worksheets/checklists (see appendices listed below;alternate but equivalent worksheets may be used as well) at least two full days before the full board or sub-committee meeting:

a) Appendices A-C for new protocols; and

b) Worksheets for Continuing Review are found in WRAIR SOP UWS-HP-618.

Note: 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) Contact the investigator to resolve significant questions/concerns before the meeting. The investigator's response should be in writing and copied to the HSPB protocol 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.) and state applicable regulations and whether they have been met.

5. The Review and Approval of the WRAIR IRB Meeting Minutes require the following:

   a. The IRB Administrative Director/Designee signs the meeting minutes and the IRB Coordinator provides the minutes to the IRB Chair/Acting Chair for review/signature.

   b. Once signed by the IRB Chair, the IRB Coordinator or Administrative Director provides the signed meeting minutes to the Commander for his/her review/signature.

   c. The final signed minutes are provided to the WRAIR IRB members in the read-ahead packet for the next IRB meeting under 'Old Business'. The committee shall note any changes, and the meeting minutes are then entered into the record.

6. Maintenance of WRAIR IRB Meeting Minutes:

a. An electronic version of the IRB meeting minutes, meeting agenda and expedited review list shall also be maintained electronically on the W:/credentialing drive (or equivalent – limited shared network) in the designated meeting and meeting minutes folders.

b. WRAIR IRB meeting minutes shall be available for inspection by authorized representatives of the USAMRDC, DoD, U.S. FDA and the U.S. Department of Health and Human Services (HHS), as appropriate and as determined by the WRAIR IRB Administrative Director.

c. In addition, investigators, representatives from cooperative research groups, and private individuals may request copies of WRAIR IRB meeting minutes under Maryland statute (House Bill 0917) or other applicable Freedom of Information (FOI) laws. Prior to making the minutes of a meeting available, the WRAIR IRB may redact confidential or privileged information (House Bill 0917); this shall be conveyed by the Public Affairs Officer. If rights of access are at all unclear, the Director, HSPB shall consult the Judge Advocate from the Office of The Surgeon General (OTSG).

d. The WRAIR IRB meeting minutes shall be stored in accordance with current applicable regulations.

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

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

8. References

Reference Number or Authors	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
WRAIR Policy #24	Submission of Protocols Involving Human Subjects, Human Information or Biospecimens, for Scientific and Ethical Review

Bankert, E. A. and Amdur, R. J.	Institutional Review Board Management and Function. Boston: Jones and Bartlett Publishers.
Amdur, R. J. and Bankert, E. A.	Institutional Review Board Member Handbook, Boston: Jones and Bartlett Publishers
DOD Instruction 3216.02	Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
HQ USAMRDC Institutional Review Board Policies and Procedures 24 November 2020	Medical Care for Research-Related Injury in Human Research
AR 15-1	Army Publishing Directorate
AR 40-68	Army Regulation, Clinical Quality Management
AR 70-25	Army Regulation, Use of Volunteers as Subjects of Research
OHRP & FDA	Minutes of Institutional Review Board (IRB) Meetings Guidance for Institutions and IRBs (2017)
OHRP & FDA	Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2018)
OHRP	Approval of Research with Conditions: OHRP Guidance (2010)
WRAIR HRPP	WRAIR Human Research Protection Program (HRPP)
SOP UWS-HP-603	Conducting Initial Protocol Review
SOP UWS-HP-606	Noncompliance Procedures
SOP UWS-HP 609	Identification and Management of Conflicts of Interest
SOP UWS-HP-610	IRB Meetings and Voting Requirements
SOP UWS-HP-613	Expedited Human Subjects Research Protocol Review
SOP UWS-HP-618	Continuing Review and Continuation Determination
SOP UWS-HP-619	Safety Reporting for Clinical Trials
SOP UWS-HP-621	Deviations and Unanticipated Problems Reporting
SOP UWS-HP-623	Submission of Human Subjects Research Protocols and Supporting Documents for Review

9. Appendices and Attachments

Appendix or Attachment Number	Title
Appendix A	WRAIR IRB Protocol Worksheet

Appendix B	WRAIR IRB International Research Worksheet
Appendix C	WRAIR IRB Primary Reviewer Worksheet
Appendix D	WRAIR IRB Agenda Template
Appendix E	WRAIR IRB Minutes Template
Appendix F	WRAIR IRB Expedited Review List Template

10. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	New SOP	08 Jan 2008
.01	Biennial review to include updates for consistency with current policies and procedures.	21 Mar 2011
.02	Review and revisions to combine with SOP UWS-HP-625, updated guidance, policies and regulations, and minor editorial clarifications.	20 July 2022