SOP Title	**CONDUCTING INITIAL REVIEW OF SUBMISSIONS TO HSPB**	SOP No.	UWS-HP-603
		Version	.02
Effective Date		Page	1 of 10

Signatures and Dates:

Author:

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

The following Standard Operating Procedure (SOP) outlines the process for conducting an initial review of protocols involving human subjects research and/or work with human human samples and/or data submitted to the Walter Reed Army Institute of Research (WRAIR) Human Subjects Protection Branch (HSPB) for review by the WRAIR Institutional Review Board (IRB). This SOP operationalizes the WRAIR Policy #24 (Submission of Protocols Involving Human Subjects, Human Information or Biospecimens, for Scientific and Ethical Review).

This applies to all categories of regulatory review, including but not limited to: Not Research (NR), Not Human Subjects Research (NHSR), Exempt/Limited IRB, Minimal Risk (MR), and Greater than Minimal Risk (GTMR).

This SOP applies to the WRAIR HSPB Director, Deputy Director, Exempt Determination Official(s) (EDO), HSPB staff, as well as the WRAIR IRB Chair (or WRAIR IRB Designee), WRAIR IRB Members, and the WRAIR Commander/ Institutional Official (IO).

2. Responsibilities

a. The WRAIR HSPB Director and Deputy Director are responsible for:

1) Designating a WRAIR HSPB reviewer for a new protocol submission (also referred to as the HSPB point of contact [POC] or Human Subjects Protection Scientist [HSPS]);

2) Reviewing or delegating the review of HSPB Protocol Evaluation Forms (PEF), as appropriate; and

3) Ensuring that HSPB staff members are trained on this SOP.

b. The EDO is responsible for reviewing and approving exempt (not those categorized as requiring limited IRB review), NR and NHSR projects.

c. WRAIR HSPB staff are responsible for reviewing human subjects research protocol submissions in accordance with applicable WRAIR and federal policies, procedures, and guidance, after requesting scientific review (as applicable and in

accordance with the SRC SOP #UWZ-002) and upon receipt of a completed protocol packet. HSPB staff document the review on a PEF (either UWS-HP-603-A1, WRAIR PEF - Appendix 1, or UWS-HP-603-A2, Abbreviated WRAIR PEF - Appendix 2) for MR and GTMR protocols or in an email/memorandum for NR, NHSR and Exempt protocols. They are also responsible for serving as the liaison between the study team and OHRO and providing any additional information, as requested, to the OHRO POC;

d. The HSPB Director, Deputy Director, WRAIR IRB Chair, WRAIR IRB Designee, EDOs and IRB Members are responsible for the review and approval/ acknowledgement, if appropriate, of protocol submissions, in accordance with this SOP.

e. The WRAIR Commander/IO is responsible for the review of the IRB approval and makes a final determination for authorization within the scope of his/her authority.

3. Investigator Guidance

The Principal Investigator (PI) or the WRAIR POC is expected to:

a. Consult early, and often with the WRAIR HSPB when a new protocol will be high priority, to ensure timely ethical review of the study. (Note: Collaborations with external institutions may also require early consults with the WRAIR Research Programs Office (RPO) or Resources Management for the applicable agreements needed);

b. Prepare the protocol submission packet in accordance with the format and content specified in WRAIR Policy #24, Submission of Protocols Involving Human Subjects, Human Information or Biospecimens, for Scientific and Ethical Review. Completion of the WRAIR HSPB Human Subjects Research Data Security Supplemental Information Form (Appendix A7) is required for all GTMR and MR studies. In addition, completion of an International Research Study Information Form (refer to Appendix C to WRAIR Policy #24) will be required for international studies. The U. S. Army Medical Research and Development Command (USAMRDC), Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO) may also require additional forms and/or may require review and approval of the protocol. The HSPB POC will coordinate submission to OHRO if their review is required;

c. Respond to and address all PEF comments within 30 days of receipt or, at the minimum, provide a status update to the HSPB within 30 days. (Note: Failure to comply could result in additional delays in the processing of the submission) If there are questions regarding the HSPB PEF, the PI should work to schedule a

teleconference with the HSPB POC to have his/her questions answered prior to submission of the response;

d. Be available to discuss the protocol with the IRB Chair (or IRB Designee). If a full board review is required, be available to address questions from IRB members prior to, or during the regularly-scheduled IRB meeting;

e. Address any concerns/questions in the "IRB Communication to the PI" (refer to UWS-HP-628, Review of Human Subjects Research by the Fully Convened WRAIR IRB) resulting from deliberations at the WRAIR IRB meeting, within 30 days or the specific timeframe requested by the IRB.

f. Respond to the HSPB PEF and/or IRB Communication to the PI, as applicable, with the following information:

1) An official memo signed through the PI's Directorate Chief, Branch Director or Designee (as applicable);

2) A point-by-point response that specifies the changes being made as well as integrating the changes into the protocol and supporting documents (tracked changes and clean versions). Note: Responses must be prescriptive and should identify the specific section(s) that were updated (e.g., Protocol Page, XX, Section "XXXXX");

3) Two electronic versions of the revised protocol and supporting documents, with updated versions; one "clean" version and one "track changes" or equivalent (e.g., "Was-Is" document) while maintaining version control (i.e. new version number(s) and date changes for any updates).

4. Materials and Equipment

N/A

5. Procedures

a. Upon receipt of a new protocol submission, according to the WRAIR Policy #24 (Submission Policy), a member of the WRAIR HSPB administrative staff:

1) Assigns a WRAIR number;

2) Sends an electronic copy of the proposed protocol and all supporting materials to the HSPB Director or Deputy Director for assignment to a WRAIR HSPB reviewer;

3) Documents the protocol in the WRAIR HSPB logbook; and

4) Opens a new entry with the initial protocol information in the HSPB database.

5) Sends a daily email log to the HSPB staff of the protocol submissions received via the HSPB mailbox.

b. The HSPB Director or Deputy Director:

Assigns the protocol to the WRAIR HSPB reviewer (also referred to as the HSPB POC or HSPS) and sends the electronic protocol documentation to them for review.

c. The WRAIR HSPB reviewer (HSPB POC or HSPS):

1) Within 3-5 days business days, reviews the submission packet for completeness as specified in the submission cover memo from the PI or e-mail correspondence and in accordance with WRAIR Policy #24 and sends an email (inclusive of the WRAIR protocol number that will be used for all future correspondences and the HSPS' contact information) to the PI/WRAIR POC acknowledging receipt of the protocol. In this initial email, the HSPB POC informs the PI/WRAIR POC as to whether or not the submission is complete and requests the missing documentation, as appropriate;

2) Assesses the preliminary risk category to identify the appropriate scientific review pathway, within 3 business days of receipt of the full submission, in accordance with WRAIR Scientific Review SOP UWZ-002;

3) Assesses the protocol to determine the need for applicable Institutional Committee Review, including review by the Radiation Safety Committee, Institutional Biosafety Committee or other review committees, within 3 business days of receipt of the full submission;

4) Reviews the complete protocol in accordance with applicable regulations within 15 business days. The reviewer may complete HSPB Protocol Worksheets and Templates (Appendices A3, A4a, and/or A4c) (prior to generating a PEF (Appendix A1), Abbreviated PEF (Appendix A2) or email/memorandum;

5) Submits the draft PEF/HSPB administrative comments to the designated HSPB senior staff (HSPB Director, Deputy Director, or EDOs) for their review within 15 business days;

6) Sends, upon approval by the HSPB senior staff, the PEF/HSPB administrative comments/email/memorandum to the WRAIR PI or WRAIR POC, associated with the protocol;

7) Maintains regular communication with the WRAIR PI or the WRAIR POC until all acceptable PEF/HSPB administrative comments/email/memorandum responses (or supported non-concurrence by the IRB Chair) and supporting documents (both clean and "track changes" versions) are received. If necessary, sends follow-up emails to the study team and/or arranges a teleconference (if appropriate) to address or discuss any unresolved questions or comments. If the comments are not acceptable after two rounds of comments from the WRAIR HSPB POC, a teleconference with the WRAIR PI or WRAIR POC should be scheduled to discuss the pending items;

8) Schedules the protocol to be reviewed by the EDO, IRB Designee or the fully convened IRB, as appropriate, or notifies the study team that the protocol is ready for external IRB review if the WRAIR is relying on another IRB for ethical review;

9) Determines which studies require review by the USAMRDC OHARO OHRO in accordance with USAMRDC Command Policy 21 or determines which studies should be issued an OHARO waiver per USAMRDC Memorandum of Record, Waiver of DoD Unique Human Subjects Protection Requirements When USAMRDC Subordinate Commands Provide Assistance to Non-DoD Institutions;

10) Submits the complete protocol package and supporting documents as needed, along with a draft IRB approval or determination memorandum/email acknowledgement, to the HSPB senior staff, for review and quality check;

11) Submits, following quality check of the IRB approval or determination memorandum or email acknowledgement, the protocol, supporting documents, and memorandum/email for signature via the appropriate review process (see steps 12, 13 and 14 below);

12) For studies eligible for review via expedited review procedures, please refer to WRAIR SOP UWS-HP-613;

13) For studies requiring review by the fully convened WRAIR IRB, please refer to WRAIR SOP UWS-HP-628;

14) Transmits a final draft of the IRB approval memorandum to the IRB Chair (or IRB Designee) or the determination memorandum to the EDO for approval

signature. For studies where WRAIR relies on another institution for IRB review, communicates with the PI that the administrative HSPB comments have been adequately addressed, and awaits receipt of the external IRB approval to submit the authorization approval memorandum to the IO. For studies that require a HRPO review and approval, the IRB Approval/ Determination memorandum/ email acknowledgement and supporting documentation are forwarded to the USAMRDC OHARO OHRO POC or designated mailbox;

15) For MR and GTMR protocols: Generates an authorization approval memorandum for the Commander/IO to review and sign (if approvable). Routes the memorandum through the appropriate electronic/automated document routing system, as applicable. All memoranda are reviewed and approved by the HSPB Director or HSPB Deputy Director (or Designee) prior to soliciting a signature from the IO. For studies that require an OHRO review, a Commander Authorization Approval memorandum is not issued until approval of the protocol is received from the USAMRDC OHARO OHRO. In some cases, the HSPB may issue a limited Commander Approval Authorization if documentation other than local ethical approval(s) remain outstanding for a study. Note: Limited Commander approval authorization cannot be issued without country specific approvals for outside the continental United States (OCONUS) studies;

16) Forwards any approval documentation or correspondences to the WRAIR PI or WRAIR POC;

17) Maintains an IRB regulatory/shadow file for the protocol, as appropriate, with copies of all versions of the protocol and all accompanying documents, as well as documentation of any communication with those involved with the protocol, its submission, review(s) and approval. This is to be maintained in an electronic format. (Note: The official regulatory file is held by the WRAIR PI or WRAIR POC); and

18) Maintains the HSPB database.

d. The WRAIR IRB Chair (or IRB Designee):

1) Reviews Limited IRB Review/MR/GTMR protocols submitted to the WRAIR HSPB for WRAIR IRB review, concurs with or updates the preliminary determination of risk level, and determines whether or not the study is eligible for expedited review in accordance with the Federal Register (Refer to WRAIR SOP UWS-HP-613);

2) Sends any review questions or concerns to the WRAIR HSPB reviewer, or forward separately to the WRAIR PI or WRAIR POC;

3) Coordinates with the HSPB reviewer and WRAIR PI or WRAIR POC, as needed, to ensure the protocol meets appropriate regulations and guidelines; and

4) Provides final approval for all limited IRB review, MR and GTMR protocols, whether reviewed via expedited review procedures or by the fully convened WRAIR IRB, and signs the IRB Approval Memorandum.

e. The WRAIR IRB Members:

See WRAIR SOP UWS-HP-616 and WRAIR SOP UWS-HP-628.

f. The EDO:

Reviews and approves/acknowledges exempt, NR and NHSR projects.

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

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

7. References

Reference Number or Authors	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
63 Federal Register (FR) 60364-60367	Categories That May be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure, 09 November 1998
Amdur, R. J. and Bankert, E. A.	Institutional Review Board Member Handbook (4th Edition), Boston: Jones and Bartlett Publishers, 2022

DoD Instruction 3216.02	Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
OHRP Guidelines	IRB Written Procedures: Guidance for Institutions and IRBs (2018)
USAMRDC Memorandum For Record	Waiver of DOD-Unique Human Subjects Protection Requirements When USAMRDC Subordinate Commands Provide Assistance to Non-DoD Institutions
USAMRDC Policy	Command Policy 21 Memorandum, Administrative Oversight Review and Approval of USAMRDC Conducted and Supported Human Subjects Research
USAMRDC Policy 26	Medical Care for Research Related Injury in Human Research conducted by the USAMRDC
WRAIR Policy #24	Submission of Protocols Involving Human Subjects, Human Information or Biospecimens, for Scientific and Ethical Review
WRAIR Policy #25	Determination that an Activity is Research Involving Human Subjects
WRAIR SOP UWZ-002	Scientific Review of Human Subjects Research Protocols
WRAIR SOP UWS-HP-613	Expedited Human Subjects Research Protocol Review
WRAIR SOP UWS-HP-616	Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB) Meetings
WRAIR SOP UWS-HP-628	Review of Human Subjects Research by the Fully Convened WRAIR Institutional Review Board

7. Appendices and Attachments

Appendix or Attachment Number	Title
UWS-HP-603-A1	WRAIR HSPB Protocol Evaluation Form (PEF)
UWS-HP-603-A2	WRAIR HSPB Abbreviated Protocol Evaluation Form (PEF)
UWS-HP-603-A3	WRAIR HSPB Protocol Checklist (Preparatory to PEF)
UWS-HP-603-A4a	WRAIR HSPB ICD Checklist (Preparatory to PEF)
UWS-HP-603-A4b	WRAIR Informed Consent Form Template
UWS-HP-603-A4c	WRAIR Reliance Checklist (Preparatory to PEF)
UWS-HP-603-A5	Investigator Qualifications Summary
UWS-HP-603-A6	Limited IRB Review
UWS-HP-603-A7	Data Security Supplemental Information Form

8. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	New SOP	09 May 2007
.01	Biennial review to include updates for consistencies with current policies and procedures	08 Sept 2010
.02	Review and revisions to incorporate updated guidance, policies, regulations, new appendices and minor editorial clarifications. In addition, revisions incorporated in response to the AHRPO report.	22 Dec 2022