| SOP Title | **EXPEDITED HUMAN SUBJECTS RESEARCH PROTOCOL REVIEW** | SOP No. | UWS-HP-613 |
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**Signatures and Dates**:

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| Author: | Signature on file | Human Subjects Protection Branch | Date |
| QA Review: | | Human Subjects Protection Branch | Date |
| Approving Authority: | | Human Subjects Protection Branch | Date |

**Review/Approval for unchanged documents**

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

The purpose of this Standard Operating Procedure (SOP) is to specify the criteria for, and process of, expedited review of human subjects research activities by the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB).

Expedited review of human subjects research protocols may be conducted by the IRB Chair or designated IRB Members, rather than by the fully convened IRB. All formally-appointed IRB Members are empowered to approve research qualifying for expedited review or to require modifications of a study prior to approval (45 Code of Federal Regulations (CFR) 46, and OHRP Guidance, 2018). The regulations, however, prohibit disapproval of any research by expedited review, and require that proposed disapprovals be referred to the full board for review and disposition. The IRB Chair or Designee may exercise all of the authority of the IRB to review research qualifying for expedited review, with the exception of disapproving such research.

Research qualifying for expedited review must meet the approval criteria defined by the Department of Health and Human Services (45 CFR 46), the Department of Defense (32 CFR 219 and DoD Instruction 3216.02) and the U.S. Food and Drug Administration (21 CFR 56). Effective 21 January 2019, certain exempt protocols may also qualify for expedited review procedures under the Limited IRB review. (See SOP UWS-HP-603-A6, Limited IRB Review.)

Consultants may assist the IRB Chair or Designee in making determinations whether to conduct expedited review of a particular protocol.

The full IRB must be notified of all research activities approved by expedited review. The IRB acknowledges receipt of this information and can either request more information or recommend full board review of any item.

This SOP applies to WRAIR IRB Chair, WRAIR IRB Chair Designee, WRAIR IRB Members, the WRAIR Principal Investigator (PI) or WRAIR Point of Contact (POC), Human Subjects Protection Branch (HSPB) staff, and the WRAIR Commander or Institutional Official (IO) acting on behalf of the WRAIR Commander.

2. **Responsibilities**

a. The WRAIR IRB Chair, or Designee, is responsible for fulfilling the responsibilities as outlined in this SOP.

b. The HSPB staff is responsible for providing administrative and technical support to the WRAIR IRB and IRB Chair.

c. The fully convened WRAIR IRB receives a list of protocol life-cycle actions approved by expedited review and can request more information or recommend full board review of any item listed.

d. The WRAIR Commander is responsible for the review of the IRB approval under expedited review and makes a final determination for implementation within the scope of his/her authority.

e. Investigator Guidance

The PI or WRAIR POC (if PI is not at WRAIR) is expected to:

1) Respond to all requests for information from the WRAIR IRB, HSPB, and the U. S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP) Human Research Protection Office (HRPO), as applicable and comply with determinations made by the IRB and WRAIR Commander regarding the research; and

2) Fulfill their responsibilities as outlined in this SOP.

## 3. Materials and Equipment

Not applicable

## 4. Procedures

a. The HSPB staff receives, reviews, and processes documents related to human subjects research (Refer to WRAIR SOP, Submission of Human Subjects Research Protocols and Supporting Documents for Review, UWS-HP-623).

b. Scientific review (as applicable) is conducted in accordance with WRAIR SOP, Scientific Review of Human Use Protocols, UWS-002.

c. Pending receipt of scientific review approval (if applicable), the HSPB Human Subjects Protection Scientist (HSPS) examines the submitted documents (Refer to WRAIR SOPs, Conducting Initial Protocol Review, UWS-HP-603 and Amendments to Human Subjects Research Protocols, UWS-HP-615) and makes a preliminary assessment as to whether or not the new protocol (or amendment) qualifies for expedited review.

d. In the case of a new protocol, if clarification is needed or if necessary documents are missing, the HSPB HSPS documents these in the HSPB protocol evaluation form (PEF) and forwards the documentation to the WRAIR HSPB Director,

Deputy Director (or Designee) for quality control (QC) review and ethical consultation prior to submitting the PEF to the PI.

e. After the QC process is complete, the HSPB HSPS forwards the PEF (or Abbreviated PEF) to the PI. The PI is given 30 days to respond to the PEF. This communication is documented and retained in the IRB protocol file.

f. Once the investigator's responses to the PEF are received, the HSPS ensures that proper version control was maintained for updated documents, or if no changes or clarifications were requested, the HSPB HSPS provides the documents to the WRAIR IRB Chair (or Designee), who, after reviewing the submitted materials, issues a secondary assessment of whether or not the protocol qualifies for expedited or Limited IRB review.

**Note**: Steps d. through f. may happen concurrently, depending upon circumstances such as the type of protocol, the scope of a proposed amendment, the urgency of need for review, or other factors.

g. Submissions that qualify for expedited and/or Limited IRB review, and have been reviewed to assess whether the activity meets the approval criteria defined in the regulations, receive one of the following recommendations by the IRB Chair or Designee:

1) Approval, identifying the specific expedited or exemption category it meets, or;

2) Approval, as a minor change to already approved research [32 CFR 219.110 (b) (1) (ii), 45 CFR 46.110 (b) (1) (ii), and 21 CFR 56.110 (b) (2)] (if submission is an amendment) or;

3) Referral to the fully convened IRB for review and determination.

h. Submissions deemed not qualified for expedited review and other submissions for which the IRB Chair or Designee recommends full board review, are placed on the agenda of the next available convened IRB meeting for full review and deliberation once the PEF items have been addressed. The PI is informed of this action and is asked to be available to the IRB Members prior to or during the meeting should they have questions.

i. When the IRB Chair (or Designee) issues either full or limited approval for minimal risk protocols (n.b., limited approval is not to be confused with the Limited IRB Review for exempt protocols) through expedited review, an official signed IRB approval memorandum is submitted to the WRAIR Commander/IO

(through the GEARS automated document routing system or other routing methods). The specific expedited review category under which it was approved is identified in the IRB approval memorandum.

j. The WRAIR Commander/IO (or IO Designee) reviews the IRB approval and makes a final determination. Research activity may begin only when the WRAIR Commander/IO, issues written full or limited Approval Authorization. An exception to this is when the activity is a request for continuation determination or a final report, wherein the IRB Chair (or Designee) is the final authority.

k. The official WRAIR IRB approval and WRAIR Commander/IO Approval Authorization memoranda are transmitted by the HSPB to the PI, the WRAIR POC, and other specified individuals.

l. New protocols and other protocol actions approved through expedited review are reported on a monthly basis to the full IRB.

m. A file is created at HSPB for the protocol, containing a copy of the documents submitted by the PI, documentation of communications between the PI and reviewers, and copies of the official memoranda.

5. **Explanation of Abbreviations, Acronyms, and Definition of Terms**

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

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| Approval Authorization | WRAIR Commander's final determination of implementation of a protocol based on the recommendation of the IRB, within the scope of his/her authority. |
| Consultant | One who gives professional advice to the IRB regarding matters in the field of his/her special knowledge or training but is not a member of the IRB. |
| Expedited Review | An expedited review is a procedure permitted by 32 CFR 219.110, 21 CFR 56.110, and 45 CFR 46.110, by which a protocol, amendment or continuing review/final report receives IRB review and approved for human subjects research activities without being reviewed at a fully convened meeting of an IRB. |

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| Human subjects research | Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, identifiable private information, or identifiable biospecimens. |
| Minimal Risk | The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves those than ordinarily encountered in daily life or during performance of routine physical or psychological examination or tests (DHHS and FDA definition) OHRP further interprets this to be relative to the daily life of a normal, healthy person. |
| Research | A systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge. |
| WRAIR IRB | WRAIR Institutional Review Board. A committee that has been formally designated to review, approve, and monitor biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects (see Army Regulation 70-25, Appendix C-1). Selection for the board is in accordance with Federal guidelines outlined in 21 CFR 56.107, 32 CFR 219, and 45 CFR 46. |

## 6. References

| Reference Number or Authors | Document Title |
|---|---|
| 32 Code of Federal Regulations (CFR) 219 | Protection of Human Subjects, |
| 45 Code of Federal Regulations (CFR) 46 | Protection of Human Subjects, updated |
| 21 Code of Federal Regulations (CFR 56 | Institutional review Boards, updated 1 April 2008. |
| 21 Code of Federal Regulations (CFR 50 | Protection of Human Subjects, updated 1 April 2008. |

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| DOD Instruction 3216.02 | Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research, 8 November 2012. |
| Amdur, R.J. and Bankert, E.A. | Institutional Review Board Management and Function. Boston: Jones and Bartlett Publishers, 2006. |
| 63 Federal register (FR) 60364-60367 | National Institutes of Health. Protection of Human Subjects: Categories that May Be reviewed by the Institutional Review Board (IRB) through an Expedited review Procedure, 9 November 1998. |
| WRAIR SOP UWS-002 | Scientific Review of Human Use Protocols |
| WRAIR SOP UWS-HP-603 | Conducting Initial Protocol Review |
| WRAIR SOP UWS-HP-615 | Amendments to Human Subjects Research Protocols |
| WRAIR SOP UWS-HP-623 | Submission of Human Subjects Research Protocols and Supporting Documents for Review |
| OHRP Guidance, 2018 | Office for Human Research Protections (OHRP) Department of Health and Human Services (HHS) Guidance on the Use of Expedited Review Procedures, May 2018 |

## 7. **Appendices and Attachments**

| Appendices or Attachment Numbers | Title |
|---|---|
| UWS-HP-613-A-A | Expedited Review Categories |
| UWS-HP-613-A-B | Checklist for Expedited Review Eligibility |

## 8. **Document Revision History**

| Version Number | Brief Description of Changes | Effective Date |
|---|---|---|
| .00 | New | 09 March 2007 |

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|---|---|---|
| .01 | Biennial Review, including organization name updates, updates to reflect current policies and procedures, and minor editorial clarifications | 12 August 2009 |
| .02 | Biennial Review, including organization name updates, updates to reflect current policies and procedures, and minor editorial clarifications | 11 April 2012 |
| .03 | Review, including organization name updates, updates to reflect current policies and procedures, and minor editorial clarifications | |