



**Walter Reed Army Institute of Research
Standard Operating Procedure**



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| SOP Title | CONTINUING REVIEW AND CONTINUATION DETERMINATION | SOP No. | UWS-HP-618 Appendix 3 |
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Appendix 3 – HSPB and WRAIR IRB Member Continuing Review Worksheet

Instructions: The Cover Sheet and Part A are to be completed by WRAIR HSPB. Parts B & C are to be completed by the IRB Reviewer. Part D is only applicable when IRB review has been deferred to another institution, and is to be completed by the WRAIR HSPB Director or Designee.

COVER SHEET

WRAIR Protocol #:

Protocol Approval Thru-Date:

HRPO Log # (if applicable):

Dates Covering the Reporting Period:

Title of Protocol:

Risk Level: Minimal Risk Greater Than Minimal Risk

Acknowledgement (Part A & D) Acceptance (Part A, B, & C)

Continuing Review Submission Received Date: _____

Principal Investigator (name):

WRAIR POC (name, if different than the PI)

CR POC (name):

HSP Scientist (name):

IRB Reviewer (name):

Sponsor (name and POC, if applicable):

Funding Organization:

Collaborating Institutions (if any):

| Name | Current Assurance # | Assurance Expiration Date |
|------|---------------------|---------------------------|
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Collaborating IRBs:

| Name | CR Approved and Date | CR Submitted | IRB Registration # |
|------|----------------------------|-----------------|--------------------------|
| | | | |
| | | | |
| | | | |

Part A – Background Information

1. Please verify that the investigator has provided adequate information for the continuation of the proposed research.

| | YES | NO | NA |
|--|--------------------------|--------------------------|--------------------------|
| a. Investigator has been using the current, approved protocol | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Investigator has been using the current, approved informed consent/assent documents | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Investigator has been using the current, approved advertising | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d. The investigator has signed the protocol compliance agreement page of the current protocol | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e. Training is current for PI and Research Monitor (if applicable) in accordance with WRAIR training or respective institutional training policies | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| f. PI verifies all training is current for all research staff on protocol | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| g. The number of subjects screened and enrolled or samples collected corresponds to the number approved. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| h. Serious and unanticipated adverse events for the whole study are summarized adequately. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| i. The following information since the last continuing review is provided: | | | |
| 1) Unexpected adverse events and unanticipated problems involving risk to subjects or others | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2) Withdrawal of subjects | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3) Complaints | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4) Protocol Deviations and Corrective Actions Taken | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5) New information provided in study reports and recent literature | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6) Updated Investigator's Brochure | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7) Independent Safety Committee or DSMB/DMC Reports | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| j. IRB approval of Continuing Review from all collaborating institutions/host nations obtained for the CR period | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| k. Recommend monitoring visit and/or independent verification of documents (if yes, see comments below) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments or Concerns:



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Part B – IRB Review of Continuing Review

Regulatory Criteria: The WRAIR IRB is required to conduct **substantive and meaningful continuing review** of research at intervals appropriate to the degree of risk, but not less than once per year. In order to approve continuation of the research, the WRAIR IRB must have sufficient information to determine that the eight required criteria codified at 32 CFR 219.111 have been satisfied.

Please verify that the investigator has submitted sufficient information to determine and the response satisfies the IRB that:

| | Yes | No |
|--|--------------------------|--------------------------|
| a. Risks remain minimized through sound research design | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Risks remain reasonable in relation to anticipated benefits | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Selection of subjects or samples is equitable | <input type="checkbox"/> | <input type="checkbox"/> |
| d. The informed consent process is adequate (or has previously been waived by the WRAIR IRB) | <input type="checkbox"/> | <input type="checkbox"/> |
| e. Documentation of informed consent is adequate (or has previously been waived) | <input type="checkbox"/> | <input type="checkbox"/> |
| f. Safety monitoring remains adequate and appropriate | <input type="checkbox"/> | <input type="checkbox"/> |
| g. Provisions for the protection of privacy of subjects and the confidentiality of data/records are adequate and appropriate | <input type="checkbox"/> | <input type="checkbox"/> |
| h. Safeguards for vulnerable subjects are adequate | <input type="checkbox"/> | <input type="checkbox"/> |
| i. The research project and progress to date are described adequately. | <input type="checkbox"/> | <input type="checkbox"/> |
| j. Recommend monitoring visit and/or independent verification of documents (if yes, see comments below) | <input type="checkbox"/> | <input type="checkbox"/> |

Comments or Concerns:



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Part C—IRB Reviewer Recommendations Summary

LEVEL OF RISK (please check):

Remains as:

- Minimal Risk** (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)
- Greater Than Minimal Risk**

OR has changed to:

- Exempt**
- Research Not Involving Human Subjects**
- Minimal Risk** (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)
- Greater Than Minimal Risk**

Device Category (please check one): **Not applicable** **Significant Risk** **Non- significant risk**

Child Category (see also Attachment 1)

- Not applicable**
- Cat. 1 (45 CFR 46.404) minimal risk**
- Cat. 2 (45 CFR 46.405) greater than minimal risk w/ the prospect of direct benefit to individual subjects**

Additional Regulations

- 21 CFR**
- 10 USC980**
- Other (Subpart, local, etc.)**

Independent Verification of No Material Changes Since Previous IRB Review (check one):

- Not Recommended**
- Recommended** (please comment):

RECOMMENDED WRAIR IRB ACTION (check one):

(To be completed by the CR Reviewer)

- Approve as submitted**
- Approvable pending minor non-substantive changes described below:**
- Referral to the Fully Convened WRAIR IRB with recommendations to:**
 - Consider major substantive changes described below:**
 - Disapprove for the reasons described below:**

Comments:



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Recommended Approval Period for next Continuing Review (check one):

- 12 months 6 months Other: _____

N/A - Closeout

Signature of Reviewer

Date

Part D—WRAIR IRB Administrative Director Recommendations Summary

IRB OF RECORD LEVEL OF RISK (please check):

Remains as:

- Minimal Risk** (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)
- Greater Than Minimal Risk**

OR has changed to:

- Exempt**
- Research Not Involving Human Subjects**
- Minimal Risk** (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)
- Greater Than Minimal Risk**

Device Category (please check one): **Not applicable**

Significant Risk

Non- significant risk

Child Category (see also Attachment 1)

- Not applicable**
- Cat. 1 (45 CFR 46.404) minimal risk**
- Cat. 2 (45 CFR 46.405) greater than minimal risk w/prospect of direct benefit to individual subjects**

RECOMMENDED HSPB ACTION (check one):

(To be completed by the CR Reviewer)

- Acknowledge as submitted**
- Acknowledge pending minor clarifications described below:**
- Recommendation to the Commander to dissolve the IAIR, and request submission of a full continuing review packet to the WRAIR IRB:**

Comments:



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Recommended Approval Period for next Continuing Review by IRB of Record (check one):

- 12 months 6 months Other: _____

Signature of Determination Official

Date