# Abbreviated Continuing Review Report (CRR) Application

**WRAIR#:**
**RV #:**
**HRPO Log #:**

**Instructions:** Please submit this completed application for all applicable research involving human subjects (refer to WRAIR SOP UWS-HP-618) to the Walter Reed Army Institute of Research (WRAIR), Human Subjects Protection Branch (HSPB) mailbox @ usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil. An alternate Abbreviated CRR template form may be used if the information is equivalent. **This abbreviated form may only be utilized if research has not yet been initiated (received WRAIR IRB approval, but no Commander Authorization OR if Commander Authorization has been received, but no subjects have been screened or enrolled. If research has initiated, a full Continuing Review Report must be submitted (Appendix 2a of the UWZ-HP 618 SOP.**))

**Continuing Review:** The WRAIR Institutional Review Board (IRB) is required to conduct "substantive and meaningful" continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, but not less than once per year. Continuing review will be conducted by the convened IRB unless the research falls into one or more of the categories appropriate for expedited review.

The information requested in this application also applies to protocols approved on or before 21 January 2019 and is designed to provide the IRB with the necessary information to make the federally required determinations codified at 32 CFR Part 219, 21 CFR Parts 50, 54, & 56, and 45 CFR Part 46 Subparts B, C and D.

Incomplete answers may result in the IRB requesting additional information or clarification. Requests for amendments to the protocol must be submitted separately from this application.

**Reporting Timeline:** To ensure timely review and approval and avoid a lapse in the IRB approval for the protocol, it is recommended that the submission of a complete continuing review packet is made 60 - 90 days prior to the established expiration date. Protocol closeout reports are due to the WRAIR HSPB 30 days following study completion.

Please contact the HSPB with any questions at (301) 319-9940 or by email at usarmy.detrick.medcom-wrair.mbx.hspb@mail.mil.

1. **Date of Report:**
2. **Dates of this reporting period** *(if the 2nd or greater report, start with the day after the last date of the previous reporting period)***:**
3. **Protocol Title, Version and Date:**
4. **WRAIR Principal Investigator/WRAIR Point of Contact** *(name, credentials, title, Department/Branch)***:**
5. **Principal Investigator, if different from above** *(name, credentials, title, Department/Branch, Institution)***:**
6. **DOD Research Monitor, if applicable** *(name, credentials, title, Institution)***:**
7. **Sponsor or Executive Authority** *(name)***: Funding Source: Work Breakdown Structure (WBS) #:**
8. **Date of WRAIR IRB approval expiration:**
9. **Please provide the following for each collaborator listed on the protocol in Table 1.**

## TABLE 1: COLLABORATING INSTITUTIONS

| | **Engaged in Human Subjects Research** | | | **NR/NHSR/Exempt Determination** |
|---|---|---|---|---|
| **A. Institution, FWA # and Expiration*** | **B. Reviewing IRB, IORG # and Expiration*** | **C. IAIR and expiration** | **D. Does institution require continuing review? Date Range of Approval** | **E. Type and Date of Determination** |
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A. Name of Collaborating Institution, FWA Number and Expiration date. *This information can be on the OHRP Website here: https://ohrp.cit.nih.gov/
B. For those institutions engaged in Human Subjects Research: Name of IRB/Ethics Board reviewing on behalf of the Collaborating Institution. Include IORG number and expiration date.
C. If a collaborating institution is relying on another IRB/Ethics Board for review, please include the expiration date of the Institutional Agreement for IRB Review (IAIR).
D. Indicate whether the reviewing IRB requires Continuing Review Reports/Annual Review and date range of approval
E. For those institutions engaged in Not Research or Not Human Subjects Research, please provide the following: Date and Type of Research Determination. The Determination must be from the Human Subjects Administration or equivalent office of the institution.

**10. Study Status and description of obstacles (if any) since initial WRAIR IRB review:**

**11. Projected date the study will begin recruitment:**

**12. Briefly summarize any study-wide reports, monitoring reports, preliminary results or any other information that has become available since study approval (if first CRR) or the last continuing review and that may affect the IRB's deliberations about the risks or benefits associated with the research:**

**13. Please provide the following information about your current literature search.**

**Date of Literature Search:**

**Search Terms and time frame covered:**

**Do the literature search results affect the risks or benefits of the human subjects?**

☐ **No** ☐ **Yes** *(If yes, please explain)***:**

**Do the literature search results affect the scientific validity of the study?**

☐ **No** ☐ **Yes** *(If yes, please explain)***:**

**Has the scientific question been answered?**

☐ **No** ☐ **Yes** *(If yes, please explain)***:**

**Are there new clinical practice guidelines that may impact the execution of the study?**

☐ **No** ☐ **Yes** *(If yes, please explain)***:**

**14. Are there any new funding sources or new conflicts of interest since the last review?**

☐ **No** ☐ **Yes** *(if "Yes", please explain)*

**15. Are any Informed Consent or Recruitment materials included in this submission?**

☐ **No** ☐ **Yes**

## Principal Investigator Statement

☐ **I certify that all investigators listed on the protocol are current in their human subjects protection training in accordance with the current WRAIR Policy: Initial and Continuing Human Subjects Protection Education and Training Requirements.**

**The point of contact for this action is the undersigned at ( ) - and @ .**

PI or WRAIR POC
Title
Department/Branch
(Date)

## Branch Director Signature

☐ **I certify that I have read and reviewed this submission for quality and completion.**

☐ **I verify the study continues to be scientifically feasible and valid, militarily relevant, and has appropriate resources (funding, equipment, personnel, etc.)**

**The point of contact for this action is the undersigned at ( ) - and @ .**

Branch Director
Department/Branch
(Date)