Continuing Review Report (CRR)

WRAIR#:

(MRMC HRPO Log #:)

Continuing Review Number *(provide sequential report number)***:**

Instructions: Please submit this completed application and continuing review memorandum for all research involving human subjects 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 CRR template form may be used if the information is equivalent.

Continuing Review: The WRAIR Institutional Review Board (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. 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 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.

Additional Forms: This report should be accompanied by a Submission Memorandum as well as the applicable documents listed in part J of this report template.

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

Part A – Background Information

1. **Date:**
2. **Protocol Title:**
3. **WRAIR Principal Investigator/WRAIR Point of Contact** *(name, title, Department/Division)***:**
4. **Principal Investigator, if different from above** *(name)***:**
5. **Research Monitor, if applicable** *(name, affiliation)***:**
6. **Sponsor or Executive Authority** *(name)***:**
7. **Funding Source:**
8. **If the WRAIR IRB did not review this study, please identify the institutional affiliation of the reviewing** *(name of institution)***:**
9. **Dates of this reporting period** *(if the 2nd or greater report, start with the day after the last date of the previous reporting period)***:**
10. **Date of WRAIR IRB approval expiration:**
11. **If this is a collaborative research study list the Collaborating Institutions, their Federal Wide Assurance# and Expiration Date, and Continuing Review Approval Date**

a. (*Name of Institutional Review Board/ERC)(FWA # and expiration date) (Continuing Review Approval Date)*

b.

c.

Part B – Current Status of Research

1. **Study initiation date:**

2. **Study completion date (or estimated date if study still ongoing):**

3. **Current Status of the approved study:**
   - ☐ **No subjects enrolled**
   - ☐ **Active – still enrolling subjects**
   - ☐ **Active – ongoing specimen/data analysis (for studies involving no subject enrollment/only specimens/data)**
   - ☐ **Closed to enrollment but subjects are still on the protocol regimen**
   - ☐ **Closed to enrollment but follow-up of subjects continues**
   - ☐ **Closed to enrollment but analysis of specimens continues**
   - ☐ **Closed to enrollment but analysis of identifiable/coded data continues**
   - ☐ **Awaiting final closure by Sponsor**

4. **Research Risk level as determined by the IRB:**
   - ☐ **Minimal Risk** ☐ **Greater than minimal risk**

5. **Research Sites (check all that apply):**
   - ☐ **WRAIR facilities i.e. Bldg 503, AFRIMS, USAMRD-W, USAMRU-K, USAMRU-G (list):**
   - ☐ **Multi-center clinical trial (list all sites):**
   - ☐ **Other collaborating institutions (provide all institution names):**

Part C – Update on Research Design and Procedures

1. **Please state the objectives of the research, a summary of the research plan and methods, and summarize your findings to date, including preliminary results where available:**

2. **Briefly summarize any study-wide reports, monitoring reports, preliminary results or any other information that has become available since study initiation (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:**

3. **Describe the results of the current literature search, along with the search terms and the date conducted. If there is any new and relevant information, published or unpublished, since study initiation (if first CRR) or the last continuing review, provide a brief summary and any impact that it may have to your**

research. If there has been no literature, include a statement indicating that a search of the literature revealed no new information for this subject matter. Please feel free to include as an attachment:

4. **Please describe any problems with or changes in the research since study initiation (if first CRR) or the last continuing review, including the following: subject recruiting; advertising; subject compensation; inclusion or exclusion criteria; costs to subjects; investigator inducements; informed consent; documentation of informed consent; privacy or confidentiality protections; safety monitoring; vulnerable subject protections:**

5. **Were all changes described above prospectively reviewed and approved by the IRB and WRAIR Command prior to implementation?**

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

6. **Describe the activities that are planned for the protocol during the coming year** *(any proposed modifications should be mentioned)***:**

Part D – Update on Subject Selection and Recruitment

1. **Number of subjects approved for this study (all sites):**

2. **Number of subjects enrolled in this study to date (all sites):**

3. **Number of subjects enrolled since the end of the reporting period of the last IRB continuing review report:**

4. **Number of additional subjects to be enrolled in this WRAIR approved study:**

5. **Have any subjects been withdrawn from this WRAIR approved study to date?**

   ☐ **No** ☐ **Yes** *(If yes, please explain how many and why)***:**

6. **Have any subjects been excluded on the basis of race, ethnic group, understanding of English, socioeconomic status, education, gender, or pregnancy?**

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

7. **Summary Tables:** *(Please complete the appropriate table(s) as they relate to the study. For example, if human subjects are being enrolled and specimens collected, then complete table 1 only. For studies solely working with specimens, then complete table 2 only).*

☐ **NUMBER OF SUBJECTS ENROLLED/WITHDRAWN/APPROVED**:

Table 1

Category	Total Number this Reporting Period	Cumulative Total
Number of Subjects originally authorized to screen: **to enroll:**		
Number Briefed:		

Number Consented & Screened:		
Number Enrolled or Randomized:		
Number Lost (deaths, other) and reason for each:		
Number Withdrawn by Investigator and reason for withdrawal(s) of each:		
Number Withdrawn (drop outs – subject withdrew him/herself) and reason for withdrawal(s) for each:		
Number Active Subjects during this reporting period:		
Number Active Subjects at the end of this reporting period:		
Number who completed all study activities:		

Note: The sum of Subjects Active, Subjects Withdrawn, Subjects Lost, and Subjects Completed must equal Subjects Enrolled

Provide a brief description of the demographics of the subjects enrolled (e.g., groups, gender, age, ethnicity, special populations). Are there any changes from the anticipated population?

<u>THIS SECTION IS TO BE USED FOR DATA/SPECIMEN ANALYSIS PROTOCOLS, ONLY. IF YOUR STUDY INVOLVES/INVOLVED THE ENROLLMENT OF SUBJECTS, ONLY USE THE TABLE ABOVE.</u>

☐ **NUMBER OF SPECIMENS AUTHORIZED/UTILIZED**:

Table 2

Category	Total Number this Reporting Period	Cumulative Total
Number of Specimens originally authorized to screen: **Number Actually Utilized:**		
Number Not Viable or Usable:		
Number Active:		
Number Completed All Study Activities:		

Note: The sum of Specimens Utilized must equal the number of Specimens Not Usable, Specimens Active, and Specimens Completed.

Provide a brief description of the use of the specimens, origin, and comment on whether there were any non-usable specimens and why there were not usable:

8. Number of subjects enrolled:

Adults (as defined by local law):

Children (as defined by local law):

9. This study involves *(check all that apply)***:**

- ☐ **Male**
- ☐ **Female**
- ☐ **U.S. Active Duty Military**
- ☐ **Foreign Active Duty Military**
- ☐ **Employees of the WRAIR/WRAIR Laboratories**
- ☐ **Healthy volunteers**
- ☐ **Pregnant Women, Human Fetuses, or Neonates**
- ☐ **Lactating Women**
- ☐ **Human Placental or Fetal Material, Embryos, or Stem Cells**
- ☐ **Children**
- ☐ **Non-English Speaking Persons** *(list languages)***:**
- ☐ **Prisoners or Juvenile Offenders**
- ☐ **Persons with Acute/Severe Mental/Physical Disabilities** *(describe)***:**
- ☐ **Persons in a Sedated/Traumatized/Crisis State** *(describe)***:**
- ☐ **Persons with Cognitive, Social, Economic, or Educational Disadvantages** *(describe)***:**

10. Please describe any changes in the inclusion/exclusion criteria for the study, explaining any changes since the last review:

11. Are subjects or treating physicians, clinicians, or researchers being compensated or paid an incentive for referring or enrolling subjects?

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

Part E – Update on Research Risks

1. Please describe what risks, side effects or discomforts (i.e., physical, psychological, social, and economic) have been observed since initiation (if first CRR) or the last continuing review report:

2. Please summarize any serious adverse events or unanticipated problems involving risks to subjects or others occurring since study initiation (if first CRR) or the last continuing review report, including their nature, severity, frequency, and resultant changes to the research or consent process:

a. Were all such events or problems previously reported as required to the IRB?

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

3. Please describe any (i) unexpected adverse events and their likely cause; (ii) withdrawal of subjects from the research; or (iii) complaints about the research occurring since study initiation (if first CRR) or the last continuing review report:

a. Have these events, withdrawals, or complaints altered the conduct of the study?

4. Please describe and discuss any deviations and the corrective action plan taken since study initiation (if first CRR) or the last continuing review report. A copy of the original report describing the deviation from the protocol may be attached if it was not previously submitted. Minor deviations should be reported with the continuing review report and major deviations should be reported when they are identified and should also be summarized in this continuing review report:

5. Was/ should the protocol be changed in light of any of these events, problems, withdrawals or complaints?

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

Part F – Multi-Center Study

1. **Is this a multi-center study?** ☐ **No** ☐ **Yes** *(If yes, please provide a brief summary of the number of subjects screened and enrolled, withdrawals, and the number and type of adverse events, unanticipated problems and deviations for each site. Please add extra columns for additional sites). <u>This may require assistance from the study Sponsor</u>***:**

Information	(Site A name)	**(Site B name)**
Number of Subjects originally authorized to screen: **to enroll:**		
Number Screened:		
Number Enrolled:		
Number Withdrawn by Investigator and reason for withdrawal(s) of each:		
Number Withdrawn (drop outs – subject withdrew him/herself) and reason for withdrawal(s) for each:		
***Number of Related Adverse Events:**		
***Number of Related Serious Adverse Events:**		
***Number of Deaths:**		
***Number of Deviations:**		

***Number of Unanticipated Problems:**		

* List the types of adverse events, deviations, and unanticipated problems that have occurred.

Part G – Additional Information

1. **Please list any other information specific to this study that you believe the IRB should consider:**

2. **As the Principal investigator/WRAIR POC, do you believe that continuation of the research is justified in light of the above information?**

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

Part H– Changes to Study Documents In Reporting Period

List any amendments to the protocol, informed consent forms, assent forms, investigator brochure, advertising or case report forms in the past reporting period. Ensure version numbers are included:

Part I – Update on Conflict of Interest Disclosure

Significant Financial Interests: A Significant Financial Interest is defined as an interest valued at greater than $10,000 or an equity ownership of more than 5% held by an investigator and/or the investigator's spouse and/or dependent children.

Financial Interests *(check all that apply)***:**

☐ **Members of the investigative team have no significant financial interests related to this research**

☐ **Members of the investigative team are disclosing the following significant financial interests** *(check all that apply)***:**

- ☐ **Salary or other payment for services (e.g., consulting fees or honoraria)**
- ☐ **Equity interests (e.g., stocks, stock options, or other ownership interests)**
- ☐ **Intellectual property rights (e.g., patents, copyrights, or royalties from such rights)**
- ☐ **Other significant financial interest that could affect, or be perceived to affect, the results of the research or educational activities funded or proposed for funding**

Other Conflicts *(check all that apply)***:**

☐ **Organizational/Institutional**

☐ **Professionsal/Relational**

☐ **Other: _____**

Part J – Attachments

1. Please attach the following items as applicable and check those attached:

- ☐ **Current IRB approved protocol with version annotated**
- ☐ **Completed Principal Investigator Signature Page for the current approved protocol**
- ☐ **Data Monitoring Committee or Data Safety Monitoring Board report(s) during this reporting period (to be included whether or not they were previously submitted to the IRB)**
- ☐ **Current IRB approved Informed consent/assent/parental permission document(s) with version annotated (clean version, to be stamped)**
- ☐ **Current Clinical investigator's brochure, package insert, PDR monograph, labeling information, where applicable**
- ☐ **Results of the current literature search, along with the search terms and the date conducted**
- ☐ **All advertisements, announcements, letters, or other recruiting materials**
- ☐ **All scales, survey instruments, questionnaires, interview scripts, etc. currently in use**
- ☐ **Serious Adverse Event and Deviation reports if not already submitted to the IRB.**
- ☐ **Copy of collaborating IRB or ethical review board approvals**
- ☐ **Any government, sponsor, or other audit or monitoring report during this reporting period for WRAIR/WRAIR sites**
- ☐ **Any available publications, presentations, abstracts, or progress reports during this reporting period that have resulted from this research**
- ☐ **Other** (e.g., tables of study data, figures, etc.)**:**

Part K– **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)