|  |
| --- |
| **WRAIR#:**      **RV #:**        **HRPO Log #:** |

**Continuing Review Report (CRR) Application**

**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@health.mil](mailto:usarmy.detrick.medcom-wrair.mbx.hspb@health.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 applicable 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 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, including extension and reclassification requests) to the protocol must be submitted separately from this application. These actions will be processed under separate cover from the Continuing Review Report, with different timelines and approval dates.

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@health.mil](mailto:usarmy.detrick.medcom-wrair.mbx.hspb@health.mil).

# Submission Checklist

1. Please utilize the checklist below to ensure all supporting documents are included:

**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**

**Current Clinical Investigator’s Brochure, package insert, Physician Desk Reference (PDR) monograph, labeling information, where applicable**

**All advertisements, announcements, letters, or other recruiting materials**

**All scales, survey instruments, questionnaires, interview scripts, data forms, etc. currently in use**

**Cumulative Serious Adverse Event and Deviation Log/Logs**

**Copy of collaborating IRB or ethical review board approvals**

**Any government, sponsor, or other audit or monitoring report during this reporting period for WRAIR sites \*See Part C, #2 – this applies only if the report will impact the IRB’s deliberations about risks or benefits.**

**Any available publications, presentations, abstracts, or progress reports during this reporting period that have resulted from this research**

**Translated documents and verification of translations, if applicable**

**CITI training certificates (dated within 3 years) for the PI, Site PI or WRAIR POC and Research Monitor (if applicable)**

**Other** (e.g., tables of study data, figures, etc.)**:**

# Part A – Background Information

1. **Date of report:**
2. **Dates of this reporting period** *(if the 2nd or later report, start with the day after the last date of the previous reporting period, end date should not be beyond the date of the report)***:**
3. **Protocol Title, Version and date:**
4. **WRAIR Principal Investigator/WRAIR Point of Contact** *(name, credentials, title, Department/Branch, Institution)***:**
5. **Principal Investigator, if different from above** *(name, credentials, title, Department/Branch, Institution)***:**
6. **Research Monitor, if applicable** *(name, credentials, title, Department/Branch, Institution)***:**
7. **Sponsor or Executive Authority** *(name)***:**
8. **Funding Source:**

**Work Breakdown Structure (WBS) #:**

**9. Date of WRAIR IRB approval expiration:**

**10.** **Please provide a list any stipulations to approval (at the time of initial approval or past Continuing Review reports). Please indicate what actions have been taken to address the stipulations.**

# Part B – Collaborators

**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** |
| 1. **Institution, FWA # and Expiration\*** | 1. **Reviewing IRB, IORG # and Expiration\*** | 1. **IAIR and expiration** | 1. **Institution require continuing review? Date Range of Approval** | **5. Type and Date of Determination** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Name of Collaborating Institution, FWA Number and Expiration date. \*This information can be on the OHRP Website here: <https://ohrp.cit.nih.gov/>
2. 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.
3. 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).
4. Indicate whether the reviewing IRB requires Continuing Review Reports/Annual Review and date range of approval
5. 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

# Part C – Current Status of Research

**1. Study initiation date:**

**2. Estimated study completion date:**

**3. Current Status of the approved study (select those that apply):**

No subjects enrolled

Active – still enrolling subjects

Active – ongoing specimen/data analysis (for studies involving no subject enrollment/only biospecimens/data)

Closed to enrollment but subjects are still undergoing protocol-specific procedures

Closed to enrollment but follow-up of subjects continues

Follow-up activities include: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Closed to enrollment but analysis of identifiable data and/or biospecimens continues

Closed to enrollment but analysis continues for data and/or biospecimens that are either anonymized or coded without link to identifiers

Awaiting final closure by Sponsor (ie database lock)

**4. Research Risk level as determined by the IRB:**

Minimal Risk (when IRB has determined that continuing review is required)

Greater than Minimal Risk

**5. Research Sites (check all that apply):**

WRAIR facilities i.e. Bldg 503, AFRIMS, USAMRD-W, USAMRD-A, USAMRD-G (list):

Multi-center clinical trial (list all sites):

Other collaborating institutions (provide all institution names):

**6. Additional Considerations (check all that apply):**

United States Food and Drug Administration (FDA) Regulated Study

Study receives funding from Health and Human Services (HHS)

# Part C – Update on Research Design and Procedures

1. **Please provide a brief summary of the study objectives and methods.**
2. **Please describe any preliminary findings that are available to date:**
3. **Briefly summarize any study-wide reports, DSMB reports, monitoring reports, 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.** *Please provide meeting requirements of DSMB or other safety committees, and the date of the most recent report.*
4. **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)***:**

1. **Please describe any obstacles since study initiation (if first CRR) or the last continuing review, for example: logistical complications, 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:**

# Part D – Update on Subject Selection and Recruitment

**Summary Tables:** *(Please complete the appropriate table(s) as they relate to the study. For example, if human subjects are being enrolled and biospecimens collected, complete Table 2 only. For studies solely working with data/biospecimens, complete Table 3 only)*. ***Please provide any relevant supplemental information in narrative form below the table.***

**TABLE 2.** **SUBJECTS ENROLLED/WITHDRAWN/APPROVED**:

|  |  |  |
| --- | --- | --- |
| Category | Total Number this Reporting Period | Cumulative Total |
| Number of Subjects originally authorized  to screen:       to enroll: | | |
| Number Briefed: |  |  |
| Number Screened: |  |  |
| Number Consented and enrolled: |  |  |
| Number lost to follow up and reason for each (described belowa): |  |  |
| Number Withdrawn by Investigator and reason for each (describe belowb): |  |  |
| Number Withdrawn/drop outs – subject withdrew him/herself and reason for each (describe belowc): |  |  |
| Number who completed all study activities: |  |  |
| Number Active Subjects at the end of this reporting period: |  |  |
| Number of additional subjects to be enrolled in the study |  |  |

**Note: The sum of Subjects Active, Subjects Withdrawn, Subjects Lost, and Subjects Completed must equal the number of Enrolled Subjects. Protocols with single day subject visits (no follow up procedures) should not have active subjects.**

1. **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)***:**

**TABLE 3.** **NUMBER OF BIOSPECIMENS/DATA AUTHORIZED/UTILIZED**:

|  |  |  |
| --- | --- | --- |
| Category | Total Number this Reporting Period | Cumulative Total |
| Number of Biospecimens/Data originally authorized to screen:  Number Actually Used: |  |  |
| Number Not Viable or Usable\*: |  |  |
| Number Currently Active: |  |  |
| Number of Biospecimens/Data that Completed All Study Analyses and Activities: |  |  |

**\*Provide a brief description of the use of the biospecimens/data, origin, and comment on whether there were any non-usable biospecimens/data and why there were not usable:**

1. **Number of subjects enrolled:**

Adults (as defined by local law):

Children (as defined by local law):

**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?**

1. **This study involves enrollment or samples from** *(check ALL that apply, even if only followed for safety)***:**

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)*:

Cognitively Impaired Persons *(describe)*:

Persons with Social, Economic, or Educational Disadvantages *(describe)*:

1. **Are subjects or treating physicians, clinicians, or researchers being compensated or paid an incentive/bonus for referring or enrolling subjects?**

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

# Part E – Update on Research Risks

1. **Does the protocol contain optional procedures?  Yes  No** *(If yes, please provide description and total number of subjects who consented for the optional procedures during this reporting period; include how many procedures were performed, if different than the number of subjects who consented)***:**
2. **Please provide a cumulative table summarizing any serious adverse events or unanticipated problems involving risks to subjects or others (UPIRTSO), including their nature, likely cause, severity, frequency, and any 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)***:**

1. **Please provide a cumulative log summarizing any other new or unanticipated risks, side effects or discomforts (e.g., psychological, social, and economic) since the initiation of the study.**
2. **Please provide a cumulative log of any complaints or unanticipated problems (including those of the community or environment) the research has faced since study initiation.**

**a. Have these events complaints altered the conduct of the study?**

**5. Please provide a cumulative table describing any deviations and the corrective actions taken since study initiation. Please indicate which deviations were major or minor and if the report was previously submitted; a copy of the original report describing the deviation from the protocol may be attached if it was not previously submitted. Please note: All deviations should be reported with the continuing review report.**

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

**No  Yes** *(If yes, please explain)***:**        **N/A**

# Part F – 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 G– Changes to Study Documents in Reporting Period

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

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

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

# Part H – Future/Anticipated Changes to Protocol, Personnel and/or Study Documents

**Describe the activities that are planned for the protocol during the coming year. List any future plans to change personnel and/or amend the protocol, informed consent forms, assent forms, investigator brochure, and advertising, or case report forms.**

# 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)**

**Compensation in the form of equipment**

**Equity interests (e.g., stocks, stock options, or other ownership interests)**

**Intellectual property rights (e.g., patents, copyrights, trademarks or royalties from such rights. Please note, this includes applications for patents, copyrights, trademarks, etc.)**

**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 of Interest *(check all that apply)*:

**Organizational/Institutional (i.e., Chain of Command)**

**Professional/Relational**

**Other (e.g., Ideology, Familial): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**N/A**

# Part J– 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)

# Part K - 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)