**Headquarters, US Army Medical Research and Development Command**

**Institutional Review Board (HQ USAMRDC IRB)**

**PRINCIPAL INVESTIGATOR AGREEMENT:**

**RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR IN HUMAN SUBJECTS RESEARCH**

**The Principal Investigator is the individual who is primarily responsible for the execution of the research. He/she is responsible for the conduct of the study, obtaining subjects’ informed consent, providing necessary reports, and maintaining study documents. The Principal Investigator will be familiar with all applicable regulations governing human subjects research, and will adhere to all requirements outlined in his/her Institution’s DoD Assurance for the Protection of Human Research Subjects as granted by the DoD, and/or by the Institution’s Federalwide Assurance granted by the Office for Human Research Protections, Department of Health and Human Services, and by his/her Institution’s Human Research Protection Program.**

**A. Initial Approval/Study Implementation**

Research activities involving human subjects, to include recruitment, screening and/or enrollment, may not commence until the study has been reviewed and approved by the HQ USAMRDC IRB (hereafter referred to as the IRB). The IRB must review and approve all study-related materials including, but not limited to, the protocol, informed consent form(s), recruitment materials, case report forms, etc.

As Principal Investigator, I acknowledge my responsibility for assuring the quality of each subject’s informed consent process in accordance with current federal, DoD, and Army regulations. This responsibility includes ensuring that any designee who obtains consent on my behalf is completely conversant with the protocol and is qualified to perform this responsibility.

I acknowledge my responsibility for ensuring that the protocol has adequate ongoing data and safety monitoring.

**B. Modifications/Amendments to the Protocol**

I agree to submit all protocol amendments, changes, and/or modifications to the IRB for review and approval prior to implementation. I will not initiate any changes in approved research, during the period for which IRB approval has already been given, without IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects or others. If such protocol changes or modifications are required, I will notify the IRB immediately.

**C. Reporting Requirements for Unanticipated Events, SAEs, Other**

I agree to promptly report (i.e., as soon as possible, but within 5 business days) all unanticipated problems involving risk to subjects or others and all serious adverse events as required in the approved protocol to the IRB by email (usarmy.detrick.medcom-usamrmc.other.irb-office@health.mil), by phone (301-619-6240), or by facsimile (301-619-4165). A complete written report will follow the initial notification. I agree to report all AEs in the continuing review or progress report for the study, as applicable, and the final study report to the IRB.

I will report immediately to the IRB the knowledge of a pending compliance inspection/visit by the US Food and Drug Administration (FDA), OHRP, or other governmental agency concerning this DoD supported research; the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies (e.g., local, state, federal) including legal or medical actions; and any instance or allegation of serious or continuing noncompliance with the regulations or requirements.

I will promptly report any significant findings that become known during the course of the research that might affect the willingness of subjects to enroll or to continue to take part in the study.

I will promptly report any change in subject status when a previously enrolled human subject becomes a prisoner.

**D. Deviations to the Protocol**

I will promptly report any deviations to the protocol that may have an effect on the safety or rights of the subject and/or the integrity of the study to the IRB. I agree to report all deviations to the protocol in the continuing review report for the study and the final study report to the IRB.

**E. Continuing Review Reports**

When required, I will submit a continuing review report for the research study to the IRB. I will report progress of the approved research to the IRB as often as requested, but not less frequently than once per year. Should the protocol not receive approval of continuation by its expiration date, all study activity, including subject recruitment, screening, enrollment, data collection and/or data analysis will be discontinued except where necessary to protect the safety of participants.

**F. Final Study Report**

I will notify the IRB upon completion of the research study and submit a final study report.

**G. Records Maintenance**

I will maintain a Study File that must be kept for three years following completion of the study (if no IND/IDE used [32 CFR 219.115 (b)]). If IND products or IDE devices are used, the file must be kept for two years after FDA approval of marketing application and can then be destroyed; or if no application is filed or approved, until two years after the study is discontinued and FDA notified [21 CFR 312.62 (c)]. If HIPAA applies, HIPAA-related documentation must be maintained for six years following completion of the study (DoD 6025.18-R, C.14.10). This Study File may be inspected at any time by representatives of the IRB, the FDA (as applicable), and/or other regulatory agencies responsible for the oversight of research. At a minimum, I will maintain the following documents in the Study File (as applicable):

* The approved protocol, supporting materials (e.g., study instruments, case report forms, recruitment materials), all protocol amendments, and all continuing review reports.
* All approval memoranda from the IRB (e.g., granting approval to initiate the study, protocol amendments, approval to continue the study).
* Correspondence with the IRB, FDA and/or other pertinent agencies.
* Other applicable committee documentation (e.g., Scientific Review Committee).
* Study tracking logs (e.g., deviation log, AE log)
* Each informed consent/assent document signed by the subject.
* Reports of unanticipated problems, adverse events (initial, follow-up, medical monitor’s report), deviations.
* Reports of any significant new findings found during the course of the study.
* All study documents generated from study data.
* Publications, abstracts, reprints resulting from study data.
* All information pertaining to an investigational drug or device (as per FDA regulations).
* Final study report and IRB closure acknowledgment.

***I have read and agree to comply with the statements above which outline my responsibilities as a Principal Investigator.***

***As the Principal Investigator of the research protocol, “\_\_\_\_INSERT TITLE HERE\_\_\_\_\_\_\_\_\_,” I assume full responsibility for the execution of this protocol. I assume full responsibility for the oversight of all research team members and their activities related to this study, and will follow my Institution’s Human Research Protections Program plan.***

**Principal Investigator Signature:**

**Printed Name:**       **Date:**