**US Army Medical Research and Development Command**

**Office of Research Protections (ORP)**

**Institutional Review Board Office**

**Continuation Report Submission Form**

The Headquarters, US Army Medical Research and Development Command Institutional Review Board (HQ USAMRDC IRB), as the IRB of Record for your protocol, is responsible for the continuing review of research to ensure that the rights and welfare of human subjects are being protected. This application for renewal of approval must be submitted to the ORP IRB Office for review by the HQ USAMRDC IRB **at least** one month prior to the expiration date to guard against lapse in IRB approval*.*

**EXPIRED RESEARCH: It is the responsibility of the Principal Investigator to ensure that the research protocol receives continuing review and re-approval by the expiration date established by the HQ USAMRDC IRB. If this form and supporting documentation for your research protocol are not submitted at least one month prior to allow the IRB to review and re-approve the protocol prior to the protocol expiration date, the protocol is considered to be expired and all study activity, including subject enrollment, data collection and/or data analysis must cease. Any research conducted under an expired protocol is in violation of the federal regulations. The federal and DOD regulations do not allow a “window” for approvals after the expiration of the approval period. It is important that your protocol be re-approved on time. If your approval expires and you wish to continue your research, the protocol must undergo HQ USAMRDC IRB review before study activities may be resumed. In some cases submission of a new protocol may be required. Timely submission of documentation required for continuing review is essential to avoid a lapse in approval.**

The HQ USAMRDC IRB must determine from the information provided on this form and supporting documents whether or not this study should be approved to continue. *Per federal and DoD regulations, “continuing review of research must be substantive and meaningful.”* Insufficient information may result in a delay in approving the continuation of your project.

**DIRECTIONS FOR FORM COMPLETION**:

 1. Use this form for **all** continuation reports. Tab through the form, entering your information in the spaces provided. Sign and date the report.

 2. E-mail this completed form and the **current version of the protocol and consent form/s** to usarmy.detrick.medcom-usamrmc.other.irb-office@mail.mil.

 3. You will be contacted by ORP IRB Office staff to confirm receipt of your continuing review report submission.

**Continuation Report**

Date of continuing review submission:

Protocol Log Number:

Complete study title:

Current IRB approval period:      **–**

What documents are you submitting in support of the continuing review? Please check all that apply.

[ ]  Current Protocol

[ ]  Informed Consent Document(s)

Is a copy of the current unstamped consent document being submitted with this application?

 [ ] Yes [ ]  No/Not applicable (if so please identify reason):

 [ ] Written consent not required (waived originally)

 [ ] Study closed to subject enrollment

[ ]  HIPAA Authorization (separate from informed consent document)

[ ]  Investigator’s Brochure/package insert

[ ]  Amendment request – please specify, and provide supporting materials

[ ]  Other:

**A. INVESTIGATOR INFORMATION**

 **1. Principal Investigator:**

Institution:

Phone Number:

E-Mail Address:

Primary Point of Contact (if not PI): Name:

 Phone:

 E-Mail Address:

 **2. Multiple Sites:**

 [ ]  No

 [ ]  Yes If yes, list site locations and provide a copy of any relevant multi-center trial reports if applicable.

 **3. List Key Study Personnel.** Use additional pages as necessary.

| Name, academic degree, rank | Role on Study | Institution | Date of most recent human subjects protection training | Phone number & e‑mail address |
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 4. Have there been any changes to key study personnel since last approval?

 [ ]  No

[ ]  Yes, If yes, explain changes.

 **5. Conflict of Interest.** Principal Investigator and key study personnel: Have there been any changes since the last protocol approval with regard to conflict of interest – financial or other – e.g., do any members of your family, or any person affiliated with the project have any financial interest, financial relationship, or administrative affiliation with any entity that is providing funds or which has rights to intellectual property resulting from this study?

[ ]  No

[ ]  Yes. If yes, please explain.

**B. UPDATE OF RESEARCH ACTIVITY TO DATE**

 1. Provide a concise overview of the protocol:

 **2. Describe the results/progress of the study since the last review and approval:**

 **3. Has this study been audited/monitored in the past year by external auditors (e.g., FDA, USAMMDA)?**

[ ]  No

[ ]  Yes. If yes, please submit a copy of the audit/monitoring report with this continuation report.

 4. Current status of study: (check relevant statements)

 [ ]  No subjects have been enrolled. Explain why:

 [ ]  Research is active (check appropriate box below):

 [ ]  Research is still open to enrollment/specimen collection

 [ ]  Research is permanently closed to subject enrollment, but study remains active for subjects receiving study interventions

 [ ]  Research remains active for long-term follow-up of subjects

 [ ]  Research remains active for data analysis only

 [ ]  Requesting closure of protocol. Explain why (e.g., research and data analysis complete, study never initiated, sponsor request):

 [ ]  Other (e.g., suspended, on hold):

5. Protocol is still accurate regarding plan for specimen/data retention and disposition at the end of the study. [ ]  Yes [ ]  No. Explain:

 **5. Type of research being conducted.**

[ ]  Research involves (or involved) accrual of human subjects (*there is some type of direct research intervention/interaction; human subjects are recruited, screened, enrolled*).

***GO TO SECTION C***

[ ]  Research **ONLY** involves (or involved) accrual of human biological specimens and/or data (*there is no direct intervention/interaction with human subjects; human specimens, substances and/or data obtained/collected/studied*).

***GO TO SECTION E***

**C. STUDY PARTICIPANTS**

 **1. Provide information on subject enrollment numbers in the table below:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Consented **to date** | Screened\* **to date** | Enrolled\*\* **to date** |
| Primary site |       |       |       |
| Multiple sites |       |       |       |
| TOTALS: |       |       |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Consented **since last review** by theHQ, USAMRDC IRB | Screened\* **since last review** by theHQ, USAMRDC IRB | Enrolled\*\* **since last review** by theHQ, USAMRDC IRB |
| Primary site |       |       |       |
| Multiple sites |       |       |       |
| TOTALS: |       |       |       |

***\*Screening:*** *A process of actively assessing a potential subject for inclusion in a study based on compatibility with pre-determined inclusion/exclusion criteria, ability and willingness to complete the study, and other factors. Informed consent must be obtained prior to screening procedures that use protected health information or involve procedures that a subject would not normally undergo.*

***\*\*Enrollment:.*** *The process of registering, entering, randomizing, or otherwise formally initiating a subject’s participation in a study. Informed consent precedes enrollment. The number of subjects consented may differ from the number of subjects enrolled in a study (e.g. a subject may give consent to participate in a study but may be determined to be ineligible upon screening; commonly called a “screen failure”). NOTE: this definition may differ from that of a study sponsor.*

 **2. Has this study experienced a low accrual rate to date?**

[ ]  No

[ ]  Yes. If yes, explain why the accrual rate is not what was anticipated:

 **3. Estimated date of enrollment completion (if completed, indicate date of completion):**

 **4. Cumulative accrual by gender (if available):**

|  |  |
| --- | --- |
| Male |       |
| Female |       |
| TOTAL: |       |

 **5. “Vulnerable populations” among the research subjects:**

 [ ]  None

 [ ]  Military personnel

 [ ]  Children (age <18 years)

 [ ]  Mentally disabled (decisionally impaired) persons

 [ ]  Prisoners

 [ ]  Pregnant women and/or neonates

 **6. Have any subjects become vulnerable, e.g., become prisoners, since the last review by the IRB?**

[ ]  No

 [ ]  Yes. If yes, please explain:

## D. SUBJECT WITHDRAWALS, COMPLAINTS

 **1. Withdrawals. During this reporting period, has any subject withdrawn or been withdrawn for any reason after signing a consent form (e.g., subject requested withdrawal, subject did not fulfill the requirements of the protocol)?**

 [ ]  No

 [ ]  Yes. If yes, please indicate the reason(s) for withdrawal(s) and the total number of subjects (**Attach a table if needed)**:

 **2. Complaints. Did any research subjects complain about any aspect of the study during the period covered by this report?**

 [ ]  No

 [ ]  Yes. If yes, please provide the number of complaint(s) and briefly describe:

**E. FOR STUDIES UTILIZING *ONLY* BIOLOGICAL SPECIMENS/DATA COLLECTION**

 **(i.e., no interaction/intervention with human participants)**

 **1. Specify type of biological specimens and/or data used in the study:**

 [ ]  Specimens. Specify type:

 [ ]  Tissue Samples. Specify type:

 [ ]  Cases/Medical Chart Review

 [ ]  Other. Specify:

**2. Provide information in the table below regarding the human data or biological specimens used in the study:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Targeted accrual goal  | Number of biological specimens and/or data samples obtained to date | Number of biological specimens and/or data obtained since last IRB review |
| TOTALS: |       |       |       |

 **3. How many more biological specimens or cases of human data will be accrued until the completion of this study?**

 **4. Estimated date of accrual completion (***if complete, indicate date of completion***):**

## F. DEVIATIONS

**Deviations. Were there any protocol deviations that occurred during this reporting period?**

 [ ]  No

 [ ]  Yes. If yes, provide a list of all protocol deviations during this reporting period and the processes implemented to prevent their recurrence.

## G. PRIVACY/CONFIDENTIALITY

**Have there been any changes in the measures in place to ensure confidentiality of data (e.g., improvements, newly identified risks)?**

[ ]  No

 [ ]  Yes. If yes, please describe the changes.

## H. UNANTICIPATED PROBLEMS & ADVERSE EVENTS

 **1. Have any of the following occurred during this reporting period? Please check all that apply.**

|  |  |
| --- | --- |
| [ ]  No[ ]  Yes | \*(a) Unanticipated Problems Involving Risks To Subjects Or Others (UPIRTSOs) If yes, were these UPIRTSOs promptly reported to the IRB? [ ] Yes [ ] No |
| [ ]  No[ ]  Yes | \*(b) Serious Adverse Events (SAEs) and/or deathsIf yes, were these SAEs promptly reported to the IRB? [ ] Yes [ ] No |
| [ ]  No[ ]  Yes | \*\*(c) Adverse Events (AEs) |

\*For (a) and (b), provide a concise list summarizing all UPIRTSOs, SAEs and/or deaths **that have previously been reported** to the IRB during this reporting period. If any have occurred that were not reported, provide an explanation regarding why, and submit the full reports.

\*\*For (c), provide **as an attachment** to this continuation report form an accounting of all AEs that have occurred during this reporting period. As appropriate, comment on whether adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure.

 **2. For studies involving FDA-regulated products, since the last review, have you received/ reviewed one or more reports of adverse drug reactions or other adverse events *from the Sponsor?***

 [ ]  No [ ]  Yes. If yes, summarize below. [ ]  N/A

## I. REVIEW OF LITERATURE

Provide documentation of a literature review update, including databases searched, dates of searches, key words and subject areas searched, either in the space below or as an attachment to this report. If no information is found, so state. Update the risk/benefit assessment or other protocol activities as necessary. Include any measures to reduce or minimize any newly identified risks. *(Rationale: when conducting continuing review, the IRB needs to determine whether any new information has emerged either from the research itself or from other sources that could alter the IRB’s previous determinations, particularly with respect to risk to subjects)*

J. CURRENT RISK/BENEFIT ASSESSMENT

Have you become aware of any relevant information or change in the risk/benefit assessment that would affect a subject’s willingness to continue participation in the study?

 [ ]  No

[ ]  Yes. If yes, please explain:

## K. MODIFICATIONS TO THE PROTOCOL

 **1. Have there been any modifications/revisions/changes to the protocol that have been implemented since the study was last approved?**

 [ ]  No

[ ]  Yes. If yes, please provide information regarding the modifications and the HQ, USAMRMC IRB-approval dates in the table below.

| Changes (use additional pagesas needed) | Date of IRB Approval | Concise Summary |
| --- | --- | --- |
| *Protocol amendment* |       |       |
| *Revised Informed Consent* |       |       |
| *Advertisement* |       |       |
| *Investigator Brochure* |       |       |
| *Change of key personnel* |       |       |
| *Data Safety Monitoring Report* |       |       |
| *Other: please specify* |       |       |

 **2. Since the last IRB review, was any new information disclosed to enrolled participants because it was considered relevant to their willingness to continue participation in the study?**

 [ ]  N/A

[ ]  No

[ ]  Yes. If so, please provide a concise summary of the disclosed information in the table below

| Source of Information | Date of IRB Approval | Concise Summary |
| --- | --- | --- |
| *Subject Letter* |       |       |
| *Revised Informed Consent* |       |       |
| *Addendum to consent form* |       |       |
| *Verbal Communication* |       |       |
| *Other: please specify* |       |       |

## L. PRINCIPAL INVESTIGATOR’S SIGNATURE

**Principal Investigator Signature:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

## DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_