**US Army Medical Research and Development Command**

**Office of Research Protections (ORP)**

**Institutional Review Board (IRB) Office**

**HQ USAMRDC Institutional Review Board**

**Protocol Closure Report Form**

**PURPOSE: Completion of this report form will constitute the final report for your research protocol and permit the IRB to conduct a final review and closure.**

**DIRECTIONS FOR FORM COMPLETION:**

 *1. Tab through the form, entering information in the spaces provided or place the cursor in a check box and click.*

 *2. Sign and date the report.*

 *3. E-mail this completed report form and all supporting documents to* *usarmy.detrick.medcom-usamrmc.other.irb-office@mail.mil**.*

ProtocolLog Number:

Principal Investigator:        Institution:

Complete protocol title:

Current IRB approval period:       -

Explain why closure of the protocol is being requested:

 [ ]  Research and data analysis is complete

 [ ]  Data analysis of aggregate dataset is ongoing with no individual subject identifiers

 [ ]  Study never initiated (Reason      )

 [ ]  Sponsor request (Reason      )

 [ ]  Withdrawal (Reason      )

 [ ]  Other: (Examples: Study closed due to adverse event(s), PI is leaving MTF)

1. **LEAD SITE/MULTIPLE SITES**

Is this a multi-site protocol?

 [ ]  No

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

 Is study being closed at all sites? [ ]  No If no, provide reason.

 [ ]  Yes

**B. RESULTS OF THE RESEARCH ACTIVITY**

Provide an overall summary of the study results and/or outcomes of the study in relation to the protocol’s stated goals.

Attach and/or provide complete citation for publications, technical reports, abstracts and/or presentations resulting from this protocol.

**C. TYPE OF RESEARCH CONDUCTED**

[ ]  Research involved accrual of human subjects (there was some type of direct research intervention/interaction; human subjects were recruited, screened, enrolled). ***GO TO SECTION D***

[ ]  Research **ONLY** involved accrual of human biological specimens and/or data (there was no direct intervention/interaction with human subjects; human specimens, substances and/or data were obtained/collected/studied). ***GO TO SECTION F***

**D. STUDY PARTICIPANTS**

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

|  | Consented Since Last IRB Review | Enrolled Since Last IRB Review |
| --- | --- | --- |
| Lead site |       |       |
| Multiple sites |       |       |
| TOTALS: |       |       |

 2. Subject Accrual

a. What was the approved number of subjects?

b. Did you meet your approved sample number?       If no, explain why.

 3. Subject Withdrawals

Has any subject withdrawn or been withdrawn for any reason after signing a consent form (*e.g., did not fulfill the requirements of the protocol*) since the last IRB review?

 [ ]  No

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

4. Subject Complaints

Did any research subjects complain about any aspect of the study since the last IRB review?

 [ ]  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. What was the targeted number of biological specimens and/or data samples to be accrued?

 2. Were the actual number of biological specimens and/or data samples obtained?

[ ]  No If no, please provide an explanation.

 [ ]  Yes If yes, how many were obtained since the last IRB review?

## F. DATA/SPECIMEN STATUS

Check all that apply regarding the plan for the retention and/or disposition of study data and samples, to include how confidentiality of data and/or samples will be maintained.

[ ]  Data was collected anonymously.

[ ]  Data has been stripped of personal or private identifiers.

[ ]  The key code has been destroyed.

[ ]  The data is no longer identifiable.

[ ]  The de-identified data will be maintained indefinitely by the PI.

[ ]  The data will be destroyed by the PI. If yes, when?

[ ]  Data will be maintained with personal or private identifiers (individually identifiable) in a secure manner approved by the IRB, but no additional research is planned at this time using this data.

[ ]  Other Please describe.

## G. DEVIATIONS

## Did any protocol deviations occur since the last IRB review?

 [ ]  No

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

## H. UNANTICIPATED PROBLEMS & ADVERSE EVENTS

 1. Did any of the following occur since the last IRB review? Please check all that apply.

|  |  |
| --- | --- |
| No Yes[ ]  [ ]  | \*(a) Unanticipated Problems Involving Risks To Subjects Or Others (UPIRTSOs) (See <http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm>l for guidance on UPIRTSOs) If yes, were these UPIRTSOs promptly reported to the IRB? [ ] Yes [ ] No |

|  |  |
| --- | --- |
| No Yes[ ]  [ ]  | \*(b) Serious Adverse Events (SAEs) and/or deaths If 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. 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 report form an accounting of all AEs that have occurred. As appropriate, comment on whether adverse events 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, have you received/reviewed one or more reports of adverse reactions or other adverse events *from the Sponsor* since the last continuing review?

 [ ]  No

[ ]  Yes If yes, please summarize.

[ ]  N/A

 3. Has there been a need to disclose information to participants in addition to that provided in the consent form?

[ ]  No

[ ]  Yes If yes, please summarize.

[ ]  N/A

## *Note: This page can be printed, signed, scanned and returned with the completed report*

## J. PRINCIPAL INVESTIGATOR’S SIGNATURE

I have notified all study personnel that the protocol is closed and that no further research activities are authorized. I commit that I will store and protect the study data and/or samples in accordance with the confidentiality measures described in the protocol.

## DATE:

**Principal Investigator Signature:**

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