**US Army Medical Research and Development Command**

**Office of Research Protections (ORP)**

**Institutional Review Board Office**

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

**PROTOCOL AMENDMENT REQUEST FORM**

**Directions:** *Place the cursor in a cell and type. The cell will expand to accommodate the text. Tab to the next field. To submit to the IRB Office, sign and date the completed Amendment Request Form and submit via email to* *usarmy.detrick.medcom-usamrmc.other.irb-office@mail.mil*

*Note that changes to the protocol* ***must not*** *be instituted until the IRB issues approval.*

**AMENDMENT #**:       **DATE**:

**PROTOCOL TITLE**:

**Principal Investigator:**

**HQ USAMRDC IRB PROTOCOL Log Number:**

**Institution’s Protocol Number (if applicable):**

**1. SUMMARY OF REQUESTED CHANGES:**

*Provide a concise summary of the requested changes.*

**2. REASON/JUSTIFICATION FOR REQUESTED CHANGES:** *Provide the rationale for the requested changes, including changes in study personnel (e.g., deployment, permanent change of station (PCS), etc.).*

**3. SPECIFIC CHANGES:** *Provide a detailed description for the requested change(s).* ***Submission of a******tracked changes/highlighted copy and clean******copy is required****. Any study team member being added to the protocol must include a current CV (dated and signed), documentation of current training in human subjects protection (within the last 3 years), and signed conflict of interest form.*

 **a. Protocol** *(update version # and/or date)*:

 **b. Consent Document** *(update version # and/or date)*:

 **c. HIPAA Authorization/Waiver** *(update version # and/or date)*:

 **d. Other**:

4. Do the proposed changes require notifying enrolled subjects or re-consenting subjects?

[ ]  No

[ ]  Yes – If yes, explain how this will be done:

**PRINCIPAL INVESTIGATOR’S RISK ASSESSMENT:**

I have reviewed the above changes to this protocol and believe that they:

[ ]  Do not change the risk-benefit status of this research

[ ]  Increase the risk associated with this research. Provide comment:

[ ]  Decrease the risk associated with this research

**PRINCIPAL INVESTIGATOR NAME/SIGNATURE:**

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

## Printed Name

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## Signature Date