

**PROTOCOL AMENDMENT FORM (FORM 4.0)**

IRB Protocol Code: Date Received (D/M/Y):

Protocol Title: Sponsor:

Principal & Sub Primary Reviewers:

Investigators:

**SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR**

 **Please check** (√) **each of the boxes that pertains to your amendment request.**

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| **1. PROTOCOL AMENDMENT*** Major
* Minor
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| **2. METHODS OR PROCEDURES*** I am requesting changes to the research methodology previously approved by the IRB.
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| **3. RISKS*** The changes that I am requesting may result in increased risks to some or all of my research subjects.
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| **4. HUMAN SUBJECTS/SPECIMENS*** I am requesting changes to the number of human subjects/specimens that I am authorized to use in my research.
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| **5. RECRUITMENT PROCEDURES*** I am requesting changes to the recruitment procedures that I am using.
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| **6. CHANGES IN THE INFORMED CONSENT FORM/ASSENT PROCEDURES OR FORM*** I am requesting changes to the informed consent form /assent procedures or form that have been approved for my research.
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| **7. CONFIDENTIALITY*** I am requesting changes to the confidentiality of participation previously approved by the IRB.
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| **8. CONFLICT OF INTEREST*** Events that have occurred which have changed the conflict of interest on the study personnel previously approved in the protocol.
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| **9. STUDY PERSONNEL*** I am requesting the following personnel changes to my protocol.
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| **Add** | **Delete** | **Name** | **Position** |
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| **10. OTHER CHANGES*** I am requesting changes to research protocol that are not addressed above.
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| **ORIGINAL** | **AMENDMENT** | **JUSTIFICATION** | **REVIEWER’S COMMENTS** |
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 **INVESTIGATOR’S ATTESTATION**

I certify that the information provided in this application is complete, accurate and necessary. The changes will not be implemented until IRB approval has been obtained.

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 Signature over Printed Name of Principal Investigator Date

*(IRB Use only)* Received by:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature over Printed Name Date

**SECTION 2: TO BE FILLED UP BY RESPECTIVE PRIMARY REVIEWERS**

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|  **Type of Review**  **Expedited Full Board**  |

* overall risk/benefit assessment
* impact on the safety & welfare of participants
* continuity of the study

 **Summary of Recommendations:**

**( ) Approved**

**( ) Additional justification/information required**

**( ) Reconsent required**

**( ) Disapproved**

 **Decision:**

 **Acknowledged by:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Name and Signature of Primary Reviewer**