

**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 |
| **2. METHODS OR PROCEDURES**   * I am requesting changes to the research methodology previously approved by the IRB. |
| **3. RISKS**   * The changes that I am requesting may result in increased risks to some or all of my research subjects. |
| **4. HUMAN SUBJECTS/SPECIMENS**   * I am requesting changes to the number of human subjects/specimens that I am authorized to use in my research. |
| **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. | | | |
| **7. CONFIDENTIALITY**   * I am requesting changes to the confidentiality of participation previously approved by the IRB. | | | |
| **8. CONFLICT OF INTEREST**   * Events that have occurred which have changed the conflict of interest on the study personnel previously approved in the protocol. | | | |
| **9. STUDY PERSONNEL**   * I am requesting the following personnel changes to my protocol. | | | |
| **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**