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PROTOCOL AMENDMENT FORM (FORM 4.1)

IRB Protocol No.	<input type="text"/>	Date Received (D/M/Y):	<input type="text"/>
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Protocol Title:	<input type="text"/>	Sponsor:	<input type="text"/>
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Principal & Sub Investigators:	<input type="text"/>	Primary Reviewer's:	<input type="text"/>
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SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR

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

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.

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
<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	<input type="checkbox"/>		

10. OTHER CHANGES

I am requesting changes to my research protocol that are not addressed above.

DETAILED DESCRIPTION OF THE AMENDMENT	REVIEWER'S COMMENT

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.

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 IRB MEMBER

Type of Review

Expedited

Full Board

Reviewer's
Comments:

Final Action:

- () Approved
- () Major Revision
- () Minor Revision
- () Disapproved
- () Others: _____

Acknowledged by:

Name of Reviewer
IRB Member

Signature

Date