INSTITUTIONAL REVIEW BOARD
Amendment / Modification Request Form

NOTE: NO CHANGES IN THE RESEARCH MAY BE IMPLEMENTED WITHOUT PRIOR IRB APPROVAL. All study protocol amendments and amendments to Informed Consent Forms must be reported to the IRB using this form. Changes to such items as surveys or questionnaires are considered changes to the study protocol. Studies may have amendments / modifications even if not actively enrolling subjects.

Principal Investigator:

Study Title:

PI Address:

PI Telephone / Email:

Date of Submission:

Amendment / Modification

Amendment / Modification Type: (select all that apply)

☐ Change in Principal Investigator or Co-Investigator

☐ Study Protocol

☐ Informed Consent Form

☐ HIPAA Form

☐ Recruitment Materials (Advertisements)

☐ Investigator's Brochure

☐ Other:

Describe the amendment / modification: Describe the requested change(s) and clearly reference materials submitted with this form. Provide a clear rationale for the proposed change(s).

Effects of the Amendment / Modification

Will the amendment / modification affect the risks or benefits to the subjects?

Yes

No

If yes, please provide a justification for the amendment / modification:

Will the amendment / modification require a change in the consent process or form?

Yes

No

If yes, please explain the nature of the change:

Study Information

Is the study open to enrollment? Yes

No

Number of Enrolled Subjects:

Attachments

Please attach the following:

- ☐ Informed Consent Form(s), if applicable – include both draft ICF with changes indicated (i.e.; highlighted, redlined, etc.) and clean version of ICF
- ☐ Study Protocol, if applicable – include both draft protocol with changes indicated (i.e.; highlighted, redlined, etc.) and clean version of study protocol
- ☐ Recruitment materials, if applicable
- ☐ Revised HIPAA Form, if applicable
- ☐ Updated Investigator's Brochure, if applicable
- ☐ Revised research materials (survey, questionnaires, instruments), if applicable
- ☐ If Change in Principal Investigator, include copy of PI's CV, DEA Registration, if applicable, and a copy of Ethics Training Certificate.

Principal Investigator Acknowledgement

I attest that the information contained herein is a true and accurate representation of my ongoing study.

P.I.'s Name: _____ Date: _____

Electronic Signature: _____

Submit Form

Please save a copy of the form for your records and submit the final form electronically by clicking the "Submit Form" to the left or at top of page.

IRB Review of Amendment / Modification Request Form (Completed by IRB Office Only)		
Date of Receipt: _____		
Is the Form Complete with Required Documents?	Yes	
	No	
Has supporting documentation been submitted, if applicable?	N/A	
	Yes	
	No	
Report returned to Investigator (indicate reason):		
Type of Review: Full Board Review	Expedited Review	
Amendment / Modification Approval Date:		