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| **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.** |

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| **Principal Investigator:** |
|  |
| **Study Title:** |
| **PI Address:** |
|  |
| **PI Telephone / Email:** |
|  |
| **Date of Submission:** |

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| **Amendment / Modification** |

Amendment / Modification Type: (select all that apply)

|  |  |
| --- | --- |
| 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).

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| **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:

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| **Study Information** |

Is the study open to enrollment? Yes

No

Number of Enrolled Subjects:

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| **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

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| **Principal Investigator Acknowledgement** |
| ***I attest that the information contained herein is a true and accurate representation of my ongoing study.*** |
| P.l.’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.***

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| **IRB Review of Amendment / Modification Request Form****(Completed by IRB Office Only)** |
| Date of Receipt: |
| Is the Form Complete with Required Documents? YesNo |
| Has supporting documentation been submitted, if applicable? N/A YesNo |
| Report returned to Investigator (indicate reason): |
| Type of Review: Full Board Review Expedited Review |
| Amendment / Modification Approval Date: |