For Submitting Changes to Previously Approved Human Subjects Research

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| **All modifications to human subjects’ research must be reviewed and approved prior to implementation.****Minor modifications** Minor modifications to previously approved projects include those that do not alter the risk–benefit assessment for the research. Examples include changes in the investigators; minor changes in the consent form(s), recruiting materials, measures, or procedures; minor changes in compensation, time of participation, or subject recruitment; or the use of a new site that is not materially different from a previously approved site. Minor modifications may also include changes to other parameters, whereby the investigator provides the subjects with more accurate information as a result of additional experience with the protocol.**Major modifications** Major modifications include significant protocol changes that would cause subjects to engage in activities not previously approved; or that involve an increased level of risk to the physical, emotional, or psychological well-being of participants (including the loss of confidentiality); or that involve a decreased benefit; or that otherwise result in alteration of the risk–benefit assessment for the research. For example, adding a new subject population, adding new measures that significantly differ from those currently approved, changing inclusion or exclusion criteria, changing the informed consent process, and changing procedures affecting subject confidentiality are all potentially major modifications. |

1. **DATE THIS REPORT WAS COMPLETED:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. **RESPONSIBLE PROJECT INVESTIGATOR**

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| Last Name:       | First Name:       | Academic Degree(s):       |
| Dept. or Unit:       | Office Address:       |  |
| Street Address:       | City:       | State:    | Zip Code:       |
| Phone:       | Fax:       | E-mail:       |
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1. **PROJECT TITLE IRB PROTOCOL NUMBER:**

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1. **MAJOR OR MINOR MODIFICATION?** In the RPI’s judgment, which category of modification is this?

[ ]  Minor [ ]  Major [ ]  Uncertain

1. **REVISED MATERIALS:** For revisions to currently approved procedures (including discontinuation of previously approved procedures, measures, etc.), or to add new procedures that were not previously approved, please resubmit the New Protocol Application Form or Application for Exemption incorporating the revisions as appropriate throughout the form. Amendments often require modification of consent forms, assent forms, measures and other relevant attachments.

**PLEASE SUPPLY THE FOLLOWING** with this Research Amendment:

1. A marked up version of the New Protocol Application or Application for Exemption and any modified attachments or consent documents. NOTE: If your computer does not allow “strike-through” or other editing on the New Protocol Application or Application for Exemption, it is acceptable to cross off deleted sections with a pen and use a highlighter to emphasize changes.
2. The **entire** New Protocol Application or Application for Exemption reflecting the revisions.
3. Revised consent documents and other relevant attachments that have changed as a result of the amendment

Mark One: Changes marked versions and final versions are: [ ]  Attached [ ]  Will Follow.

1. **DESCRIBE THE AMENDMENT.** Describe the requested change(s) and clearly reference materials submitted with this form. Provide a clear rationale for the proposed change(s). Explain whether the risk–benefit assessment for the research is likely to change as a result of the proposed amendment(s). Justify changes that will affect risks, benefits, informed consent, inclusion or exclusion criteria, the subject population(s), research sites, or the confidentiality of private, identifiable subject information.

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If additional Item 6 information is attached, check here: [ ]

1. **INVESTIGATOR ASSURANCES** The original, inked signature of the Responsible Project Investigator is required before this form can be processed. Other investigators are also responsible for these assurances and are encouraged to sign. Neither stamps nor proxy signatures are accepted in this section.

I certify that the information supplied in this form, with attachments, is complete and correct, that the modified protocol has not yet been used with any human subject, and that it will not be implemented until IRB approval has been obtained.

**NOTE: The signature of the RPI must be submitted before IRB Review (scanned or faxed signatures are acceptable).**

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| Responsible Principal investigator | Date |  | Investigator | Date |
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| Investigator | Date |  | Investigator | Date |