Change to Approved Research Form

This form should be used to obtain approval for changes (modifications or addendums) to a previously approved HPRB proposal. *All changes must be approved by the HPRB prior to implementation.* Examples of changes include but are not limited to: a change in the primary investigator (or supervisor if PI is a student), changes to the instrumentation/material, participant selection and/or recruitment, incentives/compensation for participation, procedures, and/or informed consent.

This form must be uploaded to IRBNet, **along with a modified Proposal Form clearly highlighting the proposed modifications,** as well as any additional modified documents**.** After opening your Project you will click on Designer, then Attach New document. Select Create New Package and Attach New Document again. You will be able to upload this form and the modified documents. Be sure to submit the new package when you are done.

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Advisor’s name (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRBNet ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Project title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Review type: \_\_\_ Exempt \_\_\_ Expedited \_\_\_ Full review

Initial approval date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Current approval expiration date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Previous CR approval date (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Proposed Modifications:**

1. List all desired modifications/revisions by indicating what/how you proposed initially (i.e. that which was approved) and the modifications you would now like to make.

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2. For each proposed change listed above provide a rationale for the change(s) and explain why it could not reasonably have been anticipated at the time the original proposal application was submitted.

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3. Explain whether in your judgment the proposed change(s) materially effects

 (a) the level of risk to the participants \_\_\_(YES) \_\_\_(NO), or

 (b) the relationship of the benefits to the risks of participation in the study as a whole \_\_\_(YES) \_\_\_(NO).

If any of the proposed changes increase the risk level and/or increase participants’ vulnerability status, you must provide a detailed explanation of the means by which the effect of these changes may be minimized.

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4. In your judgment does the change(s) warrant either or both of the following?

 (a) re-consenting the previously enrolled participants? \_\_\_(YES) \_\_\_(NO)

(b) a new consent form? \_\_\_(YES) \_\_\_(NO) If YES, attach a new consent form with all changes clearly highlighted.