Instructions: Complete Section I and II below, and make the applicable selection and comments for your determination under the "Finish" tab of your IRB Review task window.

If "Approve" is your determination for this modification request and you record such under the "Finish" tab, you are attesting the **criteria for approval are met** [refer to **Criteria for IRB Approval** (https://www.research.uky.edu/uploads/ori-e-irb-criteria-approval)**,** noting you may also wish to see "Guidance on Expedited Review of Minor Changes in Previously Approved Research (https://www.research.uky.edu/uploads/ori-d380000-expedited-review-minor-changes-pdf)" for what constitutes a minor change], **and your responses in Section I and II below indicate**:

1. Regulatory findings, if applicable, have been met and documented in the appropriate forms; **AND**
2. If there are Significant New Findings that might relate to a subject's willingness to continue participation which need to be relayed to the subject, the PI's proposal for communicating the information to subjects is appropriate.

If the Criteria for IRB Approval (https://www.research.uky.edu/uploads/ori-e-irb-criteria-approval) are not met, please indicate in the "Finish" tab of your IRB Review task window either:

- "minor revisions" (When non-substantive materials requested and subsequent expedited review of PI response is appropriate); **OR**
- "full review required" (Substantive clarifications or modifications regarding the protocol or informed consent document(s) required. Subsequent review at convened meeting. Use the checkbox on the "IRB Review" task page to indicate whether the PI is required to attend the meeting.)

Section I.

Any **previously approved research categories** requiring documented determinations [see list of examples (https://www.research.uky.edu/uploads/ori-e-irb-examples-research-categories)] are:

○ A. NOT affected by this modification request;

○ B. affected by this modification request [requested revisions specified in the "Finish" tab comments box apply, including what details are needed, if any, to appropriately document required determinations (e.g., Select "waiver of informed consent" and answer questions)].

Section II.

Significant new findings (e.g., from scientific literature; a procedural change; PI disclosure of financial interest; privacy/confidentiality issues, etc…) that might relate to a subject's willingness to continue participation **need to be relayed to the subject.**

- ○ No
- ○ Yes, and PI's proposal for communicating the information to subjects is appropriate.
- ○ Yes, but PI's proposal for communicating the information to subjects is not appropriate – describe revisions needed in comments box under the "Finish" tab (e.g., revise consent document & re-consent subjects; send letter to subjects).

IRB Review*

Protocol Review

Review Details | Other Reviewers | MR Signature | Finish

--> Refer to this **Criteria for IRB Approval Checklist** as needed.
--> Refer to this **Elements of Informed Consent Checklist** as needed.
--> Refer to this **Reviewer Determinations Guidance** document for info about what each determination means.

Select Your Determination

- ○ Approve
- ○ Minor Revision
- ○ Major Revision
- ○ Disapprove
- ○ Major Revision and ask ORI to invite PI to meeting
- ○ Withdrawn

☐ Serious/Continuing Non-compliance or Suspension/Termination.

Comments / Requested Revisions

☐ I am not aware of any *conflict of interest* that would prohibit me from reviewing and/or making a determination about the IRB application materials.

Save | Complete Review