

**Request for Modification Form**

Principal investigators are responsible for ongoing requirements in the conduct of previously approved or exempted research. This includes obtaining prior approval from the IRB for any modifications of the research before implementing the proposed modification.

Principal investigators seeking a modification will submit to the IRB administrator (irb@cscc.edu) this completed Request for Modification Form, along with any associated documents. This form must contain all required digital or wet ink signatures.

Modifications are categorized into minor changes and significant changes:

**Minor Modification** - A change in research related activities that do not significantly alter the risk-benefit assessment and/or the specific aims or design of the study. Examples of minor changes include, but are not limited to, the following:

* Addition or deletion of study team members
* Updating the dates of research
* Addition of procedures that do not significantly increase risk to subjects or removal of procedures that would reduce the risk to subjects
* Addition of non-sensitive questions to a survey or interview
* Addition of or minor revisions to recruitment materials, consent forms or strategies

**Significant Modification** - A change in research related activities that significantly alter the risk-benefit assessment and/or the specific aims or design of the study.

Examples of significant changes to a study may include, but are not limited to, the following:

* Addition of a new and/or separate subject population; changing inclusion or exclusion criteria
* Addition of procedures that involve an increased level of risk to the physical, emotional, or psychological well-being of subjects
* Alteration of informed consent process or procedures affecting subject confidentiality

 **Date:** Click or tap to enter a date. **Log #:** Click or tap here to enter text.

**Title of Research Project:** Click or tap here to enter text.

**Principal Investigator:**

Principal Investigator/Project Director: Click or tap here to enter text.CSCC Department or Other Institution: Click or tap here to enter text.
Email: Click or tap here to enter text.

Doctoral or Other Academic Advisor (if applicable): Click or tap here to enter text.

Institution: Click or tap here to enter text.
Email: Click or tap here to enter text.

**Category of Modification** (in the PI’s judgement, indicate the category of modification):

[ ]  Minor [ ]  Significant [ ]  Uncertain

**Describe the Requested Modification(s)**Clearly indicate if multiple modifications are being requested *(the text box will expand as needed)*:

Click or tap here to enter text.

**Describe the Rationale for the Requested Modification(s)**
If multiple modifications are being requested, ensure all have an associated rationale *(the text box will expand as needed)*:

Click or tap here to enter text.

**Does the proposed modification affect the risk-benefit assessment?** [ ]  Yes [ ]  No [ ]  Unsure

**Revised Material**

For revisions to currently approved procedures or to add new procedures, resubmit the abstract or narrative incorporating the revisions throughout. Modifications may also change consent/assent forms, recruitment materials, measures, surveys, etc. For research team member changes, identify their role in the project and provide evidence of CITI training completion (if applicable). Ensure that all new and revised documents are included with this form.

Revisions of existing documents must be indicated through track changes, highlighting, or other means.

**List all the documents submitted with this modification** *(the text box will expand as needed)*:

Click or tap here to enter text.

**Signatures:**

I have reviewed the contents of this form, with attachments, and I certify that the information provided is complete and accurate to the best of my knowledge.

*Digital or wet ink signatures are required for submission.*

Principal Investigator/Project Director Typed Name: Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Doctoral or Other Academic Advisor (if applicable): Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**FOR IRB USE ONLY
IRB Chair or Designee**

[ ]  Approved

[ ]  Modification Required

[ ]  Referred for Full IRB Review for Approval – Date of Meeting: Click or tap to enter a date.

[ ]  Disapproved

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_