

**Continuing Review Report/Final Report**

Federal guidelines (45 CRF 46.109(e)) require that Institutional Review Boards (IRB) *“conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, but not less than once per year.”*

Protocols determined to be non-research, exempt, or expedited are exempt from requirements related to continuing review.

Submit to the IRB administrator (irb@cscc.edu) this completed form and the current consent documents if the principal investigator has either enrolled participants in the project within the past year or is currently enrolling participants, along with any other associated documents that changed since the protocol was last reviewed. This form must contain all required digital or wet ink signatures.

If the research is complete, this document serves as the Final Report.

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

**Report Type (select one):**  [ ]  Continuing Review Report[ ]  Final Report

**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.

1. Summarize the study objectives and procedures *(the text box will expand as needed)*: Click or tap here to enter text.
2. Dates of Research: Start Date: Click or tap to enter a date. End Date: Click or tap to enter a date.
3. Have you completed data collection? [ ]  Yes [ ]  No [ ]  NA
4. Have you closed enrollment of new subjects for your study? [ ]  Yes [ ]  No [ ]  NA
5. Are your remaining research activities limited to data analysis? [ ]  Yes [ ]  No [ ]  NA
6. What is the date of your last Continuing Review Report? Click or tap to enter a date. [ ]  NA (this is the first report since the study was approved by the IRB)
7. Total number of subjects anticipated to be enrolled in the study: Click or tap here to enter text.
	1. Number of subjects actually enrolled in the study as of this date: Click or tap here to enter text.
	2. Number of subjects who have dropped out: Click or tap here to enter text.
	3. Number of subjects who have formally withdrawn from the study: Click or tap here to enter text.

 If subjects have withdrawn, please summarize reason(s) for withdrawal: Click or tap here to enter text.

1. Since the last review, have there been changes in the **research team or leadership** of the study?

[ ]  Yes [ ]  No

If yes, then fully describe and identify new member roles in the project and include evidence of CITI training completion with this report *(the text box will expand as needed):* Click or tap here to enter text.

1. Since the last review, have there been changes in the research **objectives**?

[ ]  Yes [ ]  No

If yes, then fully describe *(the text box will expand as needed)*: Click or tap here to enter text.

1. Since the last review, have there been changes in the research **procedures**?

[ ]  Yes [ ]  No

If yes, then fully describe and include any additional documents and questionnaires with this report *(the text box will expand as needed)*: Click or tap here to enter text.

1. Since the last review, have there been changes in the **informed consent documents or process**?

[ ]  Yes [ ]  No

If yes, then fully describe *(the text box will expand as needed)*: Click or tap here to enter text.

All current consent documents must be submitted with this report even if there were no changes

1. Since the last review, are there any changes and/or additions in **sites where data are being collected**?

[ ]  Yes [ ]  No

If yes, list additional sites or changes and include approval letters for each new site with this report *(the text box will expand as needed)*: Click or tap here to enter text.

1. Since the last review, are you aware of any **breach in confidentiality**? (e.g., unauthorized access to records)

[ ]  Yes [ ]  No

If yes, then fully describe *(the text box will expand as needed)*: Click or tap here to enter text.

1. Since the last review, have any **injuries or adverse events** occurred?

[ ]  Yes [ ]  No

If yes, then fully describe, and indicate if changes were made to the consent document, particularly in the “risks” section and describe how they are minimized and reasonable in relation to the expected benefits *(the text box will expand as needed)*: Click or tap here to enter text.

1. Since the last review, have any **unanticipated problems involving risks to subjects or others** occurred?

[ ]  Yes [ ]  No

If yes, then fully describe, and indicate if changes were made to the consent document, particularly in the “risks” section and describe how they are minimized and reasonable in relation to the expected benefits *(the text box will expand as needed)*: Click or tap here to enter text.

1. Since the last review, have there been any instances of **noncompliance** or **complaints about the research**?

[ ]  Yes [ ]  No

If yes, then fully describe *(the text box will expand as needed)*: Click or tap here to enter text.

1. Provide a listing of all **publications, presentations and reports** that have resulted from this work since the last review. If none, so state *(the text box will expand as needed)*: Click or tap here to enter text.
2. Summarize any **other relevant information**, especially information about risks associated with the research, not requested above. If none, so state *(the text box will expand as needed)*: Click or tap here to enter text.
3. List all the additional **documents submitted with this report** *(the text box will expand as needed)*: Click or tap here to enter text.
NOTE: All current consent documents must be submitted with this report even if there were no changes

**Signatures:**

As Principal Investigator, I acknowledge that I am responsible for reporting any emergent problems within five days of occurrence; that I will submit any proposed procedural modifications to the IRB for its review and approval and, except where necessary to eliminate apparent immediate hazards, no such modifications will be put into effect without prior IRB approval; that unless otherwise directed by the IRB Chair, I will renew this application with the IRB no less than annually; that the research project is being conducted in compliance with the IRB's understanding and recommendations; that the IRB is provided all the information on the research project necessary for its complete review; and that this research project will not be put into effect until final IRB approval is received.

*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 Approval – Date of Meeting: Click or tap to enter a date.
[ ]  Disapproved [ ]  Final Report (no determination is required)

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