

Today 's Date _____ Current Expiration Date _____ SCSU HRPP IRB # _____

Continuing Review Form

(To be submitted only if the study is continuing past the most recent expiration date.)

Identifying Information:

Principal Investigator: _____ Faculty/Staff Student Other

Street Address: _____ Home Phone: _____

City: _____ Work Phone: _____ E-mail: _____

State: _____ Zip: _____ FAX: _____

Department: _____ Faculty Sponsor: _____

(For student research)

Project Title: _____

Since approval by the IRB, have there been revisions in the research protocol? Please check below all revisions that apply and **explain each checked item**. Please attach pages and other material as necessary. Check final item if there have been no revisions. (Please note: If there have been revisions, a Request for Revision Form must be submitted to the IRB.)

Risk to participants has increased. For example: unanticipated risk to participants which became evident as the research progressed.

The design of the study has changed.

There have been changes in the data gathering process or data gathering instruments. Attach new or revised instruments.

Selection process and number of research participants has changed. Current number of participants. _____

The risk/benefit balance for participants has changed.

Informed consent and/or the process for obtaining informed consent has changed. Please provide a copy of the previous and current form.

The process for insuring privacy and confidentiality has changed.

There is some question regarding the safeguards in place for protection vulnerable research participants.

There have been grievances and/or complaints about this study.

There have been adverse events in the conduct of the research. Adverse Event form(s) should have been submitted to the IRB.

There have been no changes in my research protocol since the last expiration date.

In addition to responding to changes in the research please develop a brief progress report which includes significant preliminary observations. Please attach to this form.

Signature: Principal Investigator _____ Date _____