

PROTOCOL MODIFICATION SUBMISSION FORM

IRB #

Complete and submit this form together with any new or revised measures or forms attached as appendices in a **single Word or PDF file** to <u>irb@ccsu.edu</u>. Be sure to add your IRB number to the above box and include CITI certificates for all researchers as part of your submission.

Investigator Information	FACULTY MEMBERS: Check one and complete section below		STUDENTS: Complete section below
		Principal Investigator (PI) or Faculty Advisor	NOTE : Faculty advisors are to review and forward submissions to the IRB on their advisee's behalf. If modifying student research, be sure to have the faculty advisor also complete their portion of this form.
Full Name			
Email Address			
Department			
Institution Name (if other than CCSU)			

Study Title:

Nature of any change(s) since last review: Check all that apply.

Change in Principal Investigator (PI)

Addition of subjects to be recruited and/or change to recruitment process.

Change/addition to the data gathering process-- procedures, interventions or instruments used.

Change to process for insuring privacy and confidentiality.

Change to consenting process -- form/script content.

Other

None

1. Please elaborate on any change(s) noted above that were NOT previously approved by the IRB

(Use additional space and attach any additional measures, interventions and/or revised documents with this form. The IRB cannot approve modifications without the relevant documents attached as appendices to this form.):

2. Have there been any adverse incidents or unanticipated problems associated with study participants or data security since last review?

Yes
No

If yes, was the incident reported to the IRB? Please elaborate.

If the incident was not reported to the IRB, please elaborate on the incident and reason for failure to report: