



Modification Form

All modifications to currently approved research are required to have IRB review and approval prior to implementation. A modification is defined by the IRB as a change that does not alter the overall character of the original project. Changes that do not adversely alter the overall risk-benefit profile of the study may receive an expedited review. The full committee reviews proposed changes that may affect the willingness of enrolled subjects to continue participation and/or increase the risk to research subjects.

Date of most recent approval: _____

Project Title: _____

Principal Investigator: _____ Dept: _____ Phone: _____ E-mail: _____

*Student Researcher: _____ Year: _____ Phone: _____ E-mail: _____

*For student-initiated research only

Co-investigators: _____

Projected Dates of Data Collection and Analysis: _____ Begin Recruitment Date: _____ End Analysis Date: _____

Review Type: _____

1. Modification to Study Description *(attach documents as necessary)*

- Yes No Description and justification of proposed modification is attached, including a discussion of the effects on the risks and benefits to the subjects and the procedures that will be taken to manage the risk(s).
- Yes No Revised consent form is attached *(Attach 1 copy with changes highlighted, 1 master copy for file)*.
- Yes No Revised study instrument is attached.
- Yes No Revised recruitment materials are attached.

2. Changes in Personnel

- Yes No New personnel will be added to this protocol.
(Attach summary of responsibilities, qualifications, and relevant experience of all new personnel.)
- Yes No Personnel will be leaving this protocol.
(Attach summary explaining why personnel are leaving and expected date of departure.)
- Yes No Principal investigator will be changing.
(Attach letter from original PI stating the change in responsibility.)

3. Changes in Agencies

- Yes No A new facility/agency will be involved in the research activities.
(Attach a letter of support for the research from the new facility on facility letterhead containing a statement that the agency will review, abide by, and comply with the procedures approved by the College of the Holy Cross Institutional Review Board.)
- Yes No A new funding agency will be involved in the research activities.
(Attach the funding agency, grant title, agency award letter)

4. Signatures

By signing this form I certify that:

- The information I/we have provided on this form is true, complete, and accurate;
- I/we am/are familiar with and agree to abide by all relevant Federal guidelines and College of the Holy Cross policies relating to this project;
- I/we will only perform research that is approved by the IRB and not deviate in any way from this protocol without prior approval.
- My signature below verifies that this Modification Form is in compliance with procedures and/or regulations designed to protect human subjects. I understand and agree to my duties and responsibilities as Principal Investigator or Faculty Sponsor for this research project if a student project.

Principal Investigator: _____ Date: _____

Student Researcher: _____ Date: _____