



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: Select One 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: Select One

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: \_\_\_\_\_