

APPENDIX B  
 MODIFICATION FORM  
 SANTA CLARA UNIVERSITY  
 Human Subjects Committee

This form is to be used if an investigator is making any changes to the research project as approved by the HSC during the period of approval. Unless otherwise stated, submit **three (3)** copies of this form collated with **three (3)** copies of revised or additional materials. **Modifications may not be implemented until you have received approval.** The approval of this modification does not change the original period of approval of your Application for the Conduct of Research Involving Human Subjects. Complete all applicable sections of the form; if a section or does not apply to the type of modification you are making, simply type in N/A (not applicable).

DATE OF REQUEST: \_\_\_\_\_

PRINCIPAL INVESTIGATOR	DEPT./CENTER/UNIVERSITY	PHONE NUMBER: E-MAIL:
OTHER INVESTIGATORS (LIST ALL)	ADDRESS	PHONE NUMBER: E-MAIL:
FACULTY ADVISER NAME, DEPARTMENT, PHONE NUMBER, AND E-MAIL (IF STUDENT PROJECT):		
LEVEL OF REVIEW:  EXEMPT: ( )      EXPEDITED: ( )      FULL REVIEW: ( )		
PROJECT TITLE: _____		
<b>1. MODIFICATIONS TO THE GENERAL PURPOSE OF THE RESEARCH:</b>		
<b>2. DATA ACQUISITION METHOD MODIFICATIONS:</b> (check all that apply)  Questionnaire ( ) Telephone ( ) Interview ( ) Observation ( ) Experiment ( ) Secondary Source ( ) Other ( )  Explain Changes:		

**3. PROJECT DESCRIPTION MODIFICATIONS:**

Describe in detail modifications to all of the following that are applicable to your project.

- a. Study design, sequence and timing of all procedures.
  
- b. Level of deception, withholding of complete information, how, when and by whom subjects will be debriefed.
  
- c. The nature and degree of risk of possible injury, stress, discomfort, invasion of privacy, and other side effects, including psycho-social risks as well as physiological risks.
  
- d. The anticipated benefits of this research for individual subjects.
  
- e. The anticipated benefits of this research for society.

**4. CONSENT FORM MODIFICATIONS.** Describe changes to the forms and the reasons why these changes were made.

**5. SUBJECT SELECTION MODIFICATIONS.** Describe any changes you have made in how subjects are to be selected, enlisted or recruited.

**6. MODIFICATIONS TO RENUMERATION FOR SUBJECTS (gifts, payments, services provided without charge, or extra course credit).**

7. **MODIFICATIONS TO HOW SUBJECTS ARE INFORMED OF PROCEDURES, THE INTENT OF THE STUDY, AND POTENTIAL RISKS TO THEM.**

8. **MODIFICATIONS TO HOW SUBJECTS ARE INFORMED THAT THEY MAY WITHDRAW AT ANY TIME WITHOUT PENALTY.**

9. **PRIVACY AND CONFIDENTIALITY MODIFICATIONS.** Are you changing your system for maintaining subjects' privacy and confidentiality? If so, how have you changed your system, and why?

**ATTACHMENTS:** Please indicate those items we can expect to find as attachments that contain modifications of the materials submitted with your original application.

Informed consent form (as adult subjects view it) ( )

Assent form (as child subjects will view it) ( )

Questionnaire/Interview Outline ( )

Cover Letter ( )

Verbal Script ( )

Other Documentation ( ) \_\_\_\_\_

In making this modification request, I certify that the modifications described here will not be implemented without approval from the Human Subjects Committee.

SIGNATURES: Principal Investigator Faculty Adviser (for Student Research) Date

This modification has been reviewed by the Santa Clara University HSC:

FULL REVIEW ( ) EXEMPT ( ) EXPEDITED ( ) CATEGORIES: \_\_\_\_\_

APPROVED ( ) DEFERRED ( ) DISAPPROVED ( )

Project requires review more often than annual ( ) Every \_\_\_\_\_ months

Comments or modifications/conditions for approval, or reason for disapproval:

SIGNATURE \_\_\_\_\_ Date \_\_\_\_\_

[ ] Chair, HSC [ ] Member, HSC [ ] Area Representative