

APPENDIX A
 APPLICATION FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS
 SANTA CLARA UNIVERSITY
 Human Subjects Committee

It is the investigator's responsibility to provide complete information about research procedures involving human subjects. The Santa Clara University Human Subjects Committee (HSC) reviews all requests to conduct research involving human subjects. In completing the following application, be advised that the persons reviewing it may be entirely unfamiliar with the field of study involved. Present the request in computer-generated form and in non-technical terms understandable to the HSC. Please submit a copy of your complete application, an informed consent/assent form as subjects will view it, and any other material or background information as noted below that will assist the Human Subjects Committee in its review.

DATE OF REQUEST: _____

PRINCIPAL INVESTIGATOR	DEPT./CENTER/UNIVERSITY	PHONE NUMBER: EMAIL:
OTHER INVESTIGATORS (LIST ALL)	ADDRESS	PHONE NUMBER: EMAIL:
IF STUDENT APPLICATION: FACULTY ADVISER NAME, DEPARTMENT, PHONE NUMBER, E-MAIL ADDRESS: ANTICIPATED DURATION OF PROJECT: [] 1 QUARTER [] 2 QUARTERS [] ONE YEAR		
LEVEL OF REVIEW: EXEMPT: () Letter(s) that apply _____ Submit 2 copies of the application to the area representative (or HSC Chair).. EXPEDITED: () Letter(s) that apply _____ Submit 2 copies of the application to the Chair of the Human Subjects Committee. FULL REVIEW: () All other projects require full review. Submit 7 copies of the application to the Chair of the Human Subjects Committee by the deadlines indicated on the Sponsored Projects web-site		
PROJECT TITLE: _____ _____		
AGENCY SUBMITTED TO (if any):	SUBMISSION DATE:	LOCATION OF PROJECT:
1. GENERAL PURPOSE OF THE RESEARCH: (Provide relevant background information and explain in lay language why this research is important and what question(s) or hypotheses this activity is designed to answer.		

2. **DATA OBTAINED BY:** (check all that apply)

- | | | |
|-----------------------|----------------|----------------------|
| Questionnaire () | Telephone () | Interview () |
| Observation () | Experiment () | Secondary Source () |
| Other (explain) _____ | | |

3. **PROJECT DESCRIPTION:** The HSC must have sufficient information, non-technical and detailed, about what will happen with/to subjects to evaluate/estimate the risks. Assurance from the investigator, no matter how strong, will not substitute for a description of the transactions between investigator and subject. If a questionnaire is used or an interview is to be conducted, attach a copy. (When visual or auditory stimuli, chemical substances, or other measures might affect the health of the subjects, a statement from a qualified person or other appropriate documentation will aid in evaluating the nature of any risk created. In questionable cases, the HSC will require such documentation.)

- a. Summary of methodology, including the study design and sequence and timing of all study procedures that will be performed.
- b. If any deception or withholding of complete information is required for this activity, explain why this is necessary and attach a protocol explaining if, how, when, and by whom subjects will be debriefed.
- c. Describe the nature and degree of risk of possible injury, stress, discomfort, invasion of privacy, and other side effects from all procedures, drugs and devices, interviews and questionnaires. Include psycho-social risks as well as physiological risks. Include risks of withholding standard procedures or care if this is the case. Do not reference the consent form.
- d. Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None."
- e. Describe the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.

4. **SUBJECT SELECTION:**

Will subjects be less than 18 years of age? Yes () No ()

Approximately, how many subjects will you need to complete this study? _____

Briefly describe the characteristics of the subjects (e.g., age, gender, race/ethnicity):

5. How will subjects be selected, enlisted or recruited? Describe the subject recruitment strategies you will use for each group of subjects. Address who will approach subjects to take part in the study. Attach advertisements, flyers, contact letters, telephone contact protocols, etc. Also attach letters of cooperation from schools and if applicable, other agencies or institutions involved in subject recruitment.

6. Will you give subjects gifts, payments, services without charge, or extra course credit? no yes
If yes, explain. If extra course credit is offered, be sure to address the alternative means by which students can accrue extra-credit should they not wish to participate in the study.
7. How will subjects be informed of procedures, intent of the study, and potential risks to them? Submit written copy of what the subjects will receive. (Please see website for sample informational letters or informed consent forms.)
8. How will subjects be informed they may withdraw at any time without penalty? Submit written instructions that the subject will receive.
9. a. How will subjects' privacy be maintained and confidentiality guaranteed? (Will you record any direct subject identifiers (e.g., names, Social Security numbers, student identification numbers, addresses? If so, why is this necessary and describe the coding system you will use to protect against disclosure. Will you retain a link between study code numbers and direct identifiers after the data collection is complete? If so, why is this necessary and for how long will you keep this link?)
- b. Will you make audio-visual or tape recordings or photographs of subjects. No Yes
If "Yes," explain what type of recordings you will make, how long you will keep them, how they will be disposed of after completion of the study, and if anyone other than the members of the research team will be able to see them. Note: informed consent form will require release statement for videotaping or relinquishing confidentiality.

ATTACHMENTS: Please indicate those items we can expect to find as attachments.

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 application, I certify that I have read and understand the Policies and Procedures for Projects that Involve Human Subjects and that I intend to comply with the letter and spirit of the University Policy. Significant changes in the protocol will be submitted to the HSC for written approval prior to these changes being put into practice. Informed consent/assent records of the subjects will be kept for at least three (3) years after the completion of the research. (In the case of student research, faculty adviser signature certifies that the supervising faculty member has reviewed human subjects guidelines with students and endorses the application.)

SIGNATURES: Principal Investigator

Faculty Adviser (for Student Research)

Date

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FOR COMMITTEE USE ONLY

This application 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

Approval is granted for one year from the date of approval. A report must be filed at the time of project completion or at the end of one year (whichever comes first). An application for renewal must be filed if the investigator wishes to continue the project beyond the one-year approval given.