

Application for the Use of Human Subjects

Part A – Application Information

1. Title of the Study:	
2. Principal Investigator:	
Title:	Dept:
Address (+ ZIP):	
Phone:	Email:
3. Co-Investigator(s): (Name & Affiliation)	
4. Research Originated By: (Check One) <input type="checkbox"/> Faculty <input type="checkbox"/> Student <input type="checkbox"/> Staff	

Part B - Research Study Synopsis

1. Short Study Description:
2. Study Length What is the duration of the study?
3. Location of Research Where will the research take place?
4. Subject Information: a. Number of Subjects: b. Gender of Subjects: c. Ages of Subjects:
5. Potentially Vulnerable Populations: (Check All that Apply) <input type="checkbox"/> Children <input type="checkbox"/> Pregnant Women <input type="checkbox"/> Cognitively Impaired <input type="checkbox"/> Prisoners <input type="checkbox"/> Institutionalized <input type="checkbox"/> Faculty's Own Students <input type="checkbox"/> Other. Please describe:
6. Non-English Speaking Subjects a. Will subjects who do not understand English participate in the research: <input type="checkbox"/> Yes <input type="checkbox"/> No b. If yes, describe your resources to communicate with the subjects: c. Into what language(s) will the consent form be translated? (Attach translations)
7. Dissemination of Research Findings a. Will the research be published? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, where if known? b. Will the research be presented? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, where if known?
8. External Funding a. Are you seeking external funding? <input type="checkbox"/> Yes <input type="checkbox"/> No What agency? b. Have you received funding? <input type="checkbox"/> Yes <input type="checkbox"/> No Dollar amount?
9. Method of Recruitment: (Check All that Apply) <input type="checkbox"/> Flyer <input type="checkbox"/> Classroom Announcement <input type="checkbox"/> Letter to Subjects <input type="checkbox"/> Third Party <input type="checkbox"/> Random <input type="checkbox"/> Other
10. Payment to Subjects a. Will subjects be compensated for participation? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please indicate amount: b. Form of Payment: <input type="checkbox"/> Cash <input type="checkbox"/> Check <input type="checkbox"/> Gift Certificate <input type="checkbox"/> Voucher <input type="checkbox"/> 1099 <input type="checkbox"/> Other c. Will Payment be prorated? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please explain: d. When will the subject be paid? <input type="checkbox"/> Each Visit <input type="checkbox"/> Study Completion <input type="checkbox"/> Other

11. Extra Credit

a. Will subjects be offered extra credit? Yes No

b. If yes, describe the alternative:

12. Risks: Identify all potential risks/discomforts to subjects.

13. Benefits:

a. Are there direct benefits to participants? Yes No If yes, please list.

b. Are there potential benefits to society? Yes No If yes, please list.

14. Study Procedures:

a. What will be the duration of the subjects' participation?

b. List all procedures/questionnaires used for the research study.

15. Informed Consent:

a. Briefly describe your process to obtain consent:

16. Confidentiality:

a. Are the subject's social security number or any identifier being used?

Yes No If yes, describe and explain reasons.

b. Briefly describe provisions made to maintain confidentiality of data, including who will have access to raw data, what will be done with the data files, survey instruments, discs, CD's, tapes, etc.

c. Will raw data be made available to anyone other than the PI and immediate study personnel? Yes No
If yes, describe the procedure for sharing data. Include with whom it will be shared, how and why.

Part C – Assurance Document

The attached investigation involves the use of human subjects. I understand the college's policy concerning research involving human subjects and I agree:

1. To obtain voluntary and informed consent of all subjects who are to participate in this project.
2. To report immediately to the IRB any unanticipated effects on subjects which become apparent during the course of, or as a result of, the experimentation and the actions taken.
3. To obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in the approved consent document.
4. To safeguard the confidentiality of research subjects and the data collected when the approved level of research requires it.
5. All surveys must be scheduled through the Office of Institutional Research as per SJC procedures. This process is necessary to ensure the consideration of staff, faculty, student, and community members' time and avoid duplication of effort. Please contact Candace Gilfillan at 566-3035 or gilfillanc@sanjuancollege.edu if your research involves a survey.

Signature of the Principal Investigator: _____

Date: _____

Faculty Sponsor Signature Necessary for All Student Submissions.

“I have read and reviewed this proposal and certify that it is ready for review by the IRB. I have worked with the student to prepare this research protocol. I agree to mentor the student during the research project. I have received Human Subjects in Research training.” (PLEASE ATTACH A COPY OF THE TRAINING CERTIFICATE)

Faculty Sponsor: _____
Signature Printed Name

Part D - Synopsis of the Proposal

Part D should only be 5 pages or less (not including instruments, consent forms, etc.). Please use **12pt** font, **page numbers** and the **headings** noted below.

1. Specific Aims
2. Hypothesis
3. Background and Significance
4. Description of Subjects
5. Confidentiality
6. Method or Procedures
7. Risks
8. Benefits
9. Compensation
10. References
11. Qualifications

Include the following information as necessary in the appropriate appendix.

Part E - Copy of Consent Document

Part F - Questionnaires, Surveys, Instruments, Interview questions, etc.

For IRB Use			
<input type="checkbox"/> Expedited Review	<input type="checkbox"/> Full Review	Date _____	
<input type="checkbox"/> Reviewed	<input type="checkbox"/> Approved	<input type="checkbox"/> Rejected	<input type="checkbox"/> Returned for Revision
<input type="checkbox"/> Returned for Additional Information _____			

Signatures _____, IRB Chair			
_____		_____	
_____		_____	
_____		_____	