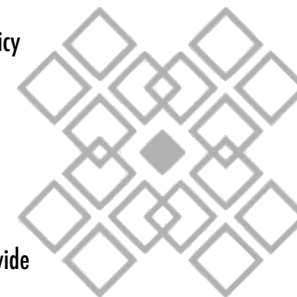




## IRB Made Easy (We Hope)

## What is the Institutional Review Board

- 10-15 member committee
- Reviews all research at SJSU...ensure compliance with university & federal policy
- "Research" ...information published or disseminated that contributes to generalizable knowledge
- "Human Subjects" ...research involving people who physically participate or provide information through interviews, surveys, observation, or identifiable information in files, databases, etc.



## A Bit of History - Nuremberg Code

- Standards to judge human experimentation
- "the voluntary consent of the human subject is absolutely essential."
- Minimize risk & harm
- Favorable risk/benefit ratio
- Qualified investigators using appropriate research design
- Freedom of subject to withdraw at any time

## Key San José State Policies

- Policy for Protection of Human Research Subjects
  - (<http://www.sjsu.edu/senate/S08-7.htm>)
- Institutional Review Board - Human Subjects Training for Investigators
  - (<http://www.sjsu.edu/senate/S05-3.htm>)



SAN JOSÉ STATE  
UNIVERSITY

## Submitting Your IRB "Protocol"

1. Sponsoring professor (your advisor) completes training...DONE!
2. Prepare your IRB application, protocol narrative, data instruments, consent forms, etc....MORE ON THIS IN A BIT.
3. Advisor approves IRB protocol
4. Submit IRB protocol to Alena Filip

• (IRB/Thesis Coordinator, Research & Graduate Studies, 924-2479, [alena.filip@sjsu.edu](mailto:alena.filip@sjsu.edu))

## Protocol Components: The Application

1. "Request to Use Human Subjects in Research"

• [http://www.sjsu.edu/gradstudies/docs/irb\\_application.doc](http://www.sjsu.edu/gradstudies/docs/irb_application.doc)

2. Don't forget "Responsible Faculty Member" section

San Jose State University  
Human Subjects-Institutional Review Board  
Request to Use Human Subjects in Research  
Cover Sheet

*For Help in (most) fill-in fields, push F1.*

Date submitted: | | Project Period: From: | | To: | |

Funded by: | |

Name: | | Department: | |

Phone Number: | Work: | | During: | | Home: | | During: | |

Cell Phone: | | Pager: | | E-mail address: | |

Address: | |

Select one:  SJSU Student  If Non-SJSU Investigator, SJSU contact: | |

Title of proposed project: | |

Abstract: (if possible, attach on a separate sheet) | |

Number of Subjects: | | Age of Subjects: | |

Type of Subjects: | |

Proposed Research Method: | |

---

**Responsible Faculty Member Form**

**Must be submitted with all student research protocols.**

Title of proposed project: | |

Student Investigator(s): | |

Responsible Faculty Member(s): | |

I (we), the undersigned, have reviewed the above named study and believe the research conforms to federal, state, and SJSU policy for the protection of human subjects in research. Further, I (we) will monitor the course and conduct of the proposed research.

Faculty Signature(s): | | Date: | | Department: | |

## Protocol Components: The Narrative

1. Abstract
2. Statement of Purpose & Justification
3. Research Question/Hypothesis to be addressed

FIVE WOUNDS/BROOKWOOD TERRACE COMMUNITY PLANNING WORKSHOPS  
STATEMENT OF PURPOSE AND JUSTIFICATION

The purpose of this neighborhood planning process instrument is to prepare a neighborhood plan for San Jose's Five Wounds/ Brookwood Terrace (FWBT) neighborhood. There is no reasonable alternative way to gather information on residents' priorities without seeking information from and opinions of the residents' about their neighborhood environment. The findings of this planning effort will feed into the larger CommUniverCity collaboration with the FWBT neighborhood and the City of San Jose.

CommUniverCity San Jose is a collaboration between the San Jose neighborhood of Five Wounds / Brookwood Terrace, San Jose State University, and the City of San Jose. This neighborhood was selected because it was judged underserved by the City and other agencies and because they it is part of the City's Strong Neighborhood Initiative (SNI), which means the City is investing extra funding and staff time in it's improvement. The SNI process includes an elected Neighborhood Advisory Council (NAC) composed of local residents which reviews and must approve all projects. They have welcomed CommUniverCity, which will concentrate a range of service learning projects and classes in these neighborhoods over a period of five years or longer in hopes that by concentrating our efforts and extending them over a substantial time, we can have a significant impact. The SJSU CommUniverCity projects will be supported by the City and approved by the NAC. In order to measure the impact of the CommUniverCity projects, several outcomes/assessment procedures are being developed. The proposed citizen participation process will serve as an instrument to determine neighborhood priorities for CommUniverCity to focus on.

**HYPOTHESIS**

The hypothesis is that residents' priorities will focus on the following aspects of the community: a) education; b) health; c) affordable housing; d) community services; e) the creation of a "town square" next to the Five Wounds church; f) revitalization of the commercial corridor along East Santa Clara Street and Alam Road; g) development along the abandoned Southern Pacific railroad tracks; h) walkability (or means to make the neighborhood more pedestrian-friendly).

## Protocol Components: The Narrative cont.

4. Methods Section
- **Subjects:** #, age, type, selection procedure, rationale, benefits, risks, compensation, identification in report
  - **Materials & Devices:** test materials (e.g. survey protocol), devices to be used (e.g. tape recorder)
  - **Procedures:** what subjects will be asked to do (step-by-step), where, when, by whom will the research be done
  - **Confidentiality:** will subjects be identified, methods to protect confidentiality, how is data protected (password-protected file, locked cabinet, etc.)

## Methods Section Example

### b) Procedure for selecting subjects

For each city identified as having bus lanes worth including in the project, we will identify the public agency employees with the most experience planning and managing the bus lane project.

### c) Rationale for employing the type of subjects selected

The subjects will provide expert information on the effectiveness of different bus lane operation and enforcement strategies.

### d) How subjects are expected to benefit from participation in the study

Subjects are not expected to benefit from this study other than to the extent that they value contributing their knowledge and expertise to research and informed decision making. They may benefit indirectly from the knowledge gained from the research after it is completed. Subjects will receive no direct, tangible benefits. Participants will not be offered any financial reward or other incentive to participate.

### e) Risks to subjects anticipated from participation in the study

There are no anticipated risks to the subjects.

### f) Compensation

## Protocol Components: Informed Consent

- Document how you will obtain "Informed Consent"



Additional Information for Research Participants in the Study  
"Bus Priority Lane Enforcement and Availability in Congested Urban Centers"  
(Responsible Investigator: Asha Weinstein Agrawal)

Please read carefully the following information, which explains your rights as a research participant.

1. You have been asked to participate in a study researching the investigating best practices in the design, implementation and enforcement of priority bus lanes.
2. You will be asked to participate in a 20 or 30 minute phone interview during which you will be asked questions about your experience with the design, implementation and enforcement of priority bus lanes.
3. There is no anticipated risk to you from participating in this project.
4. There is no anticipated direct benefit to you from participating in this project other than the extent to which you value contributing your knowledge to helping local governments as they design and revisit their bus priority lane enforcement strategies.
5. Unless you ask request otherwise, your name and affiliation will be included at the end of the final report in a list of persons interviewed for the study. In addition, where your comments are especially insightful, the report may quote you and identify you by name. The interviewer will assume that your comments are on-the-record and that you agree to being quoted, unless you instruct the interviewer otherwise. If you wish to share any comments "off-the-record," simply let the interviewer know, and that information will be kept strictly confidential within the research team. Finally, to ensure that your views are represented accurately, if the researchers wish to attribute a quotation to you personally, then you will be emailed a draft of that section of the report that you may review for accuracy.

- Attach a copy of consent form on SJSU letterhead

## Protocol Components: Data Instrument(s)

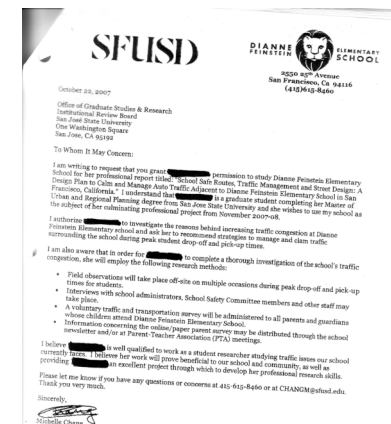
- Attach copies of data instruments (surveys, interview protocol, etc.)

### Survey Questionnaire

1. How long have you lived in this neighborhood?  
1= Less than 2 years  
2= 3 to 5 years  
3= 6 to 10 years  
4= More than 10 years  
7= Can not choose/Refused
2. What is your age?  
1= 18 to 34 years  
2= 35 to 54 years  
3= 55 to 74 years  
4= 75 years or older  
7= Can not choose/Refused
3. How many children under 18 years old are there in your household?  
0= 0 (please skip questions 4 to 8)  
1= 1  
2= 2  
3= 3  
4= 4 or more  
7= Can not choose/Refused (please skip questions 4 to 8)
4. How many children go to elementary school?  
0= None (skip question 5)  
1= 1  
2= 2  
3= 3 or more  
7= Can not choose/Refused (skip question 5)
5. Which elementary school do the children go to?  
1= Anne Darling Elementary School  
2= Clinder Elementary School  
3= McKinley Elementary School  
4= Other (please print) \_\_\_\_\_  
7= Can not choose/Refused

## Protocol Components: Other Elements

- Permission from participating agencies (e.g. if you are doing your research as part of work project, conducting research at a particular site such as a school, etc.)



## URBP 298 Website Resources

Handouts:

- [Research questions](#)
- [On-line research tips](#)

February 2 - Class 2

Lecture: Conducting case studies; conducting interviews; the IRB process

Readings:

- [Read about the IRB process and review the forms used to put together an application at <http://www.sjsu.edu/gradstudies/irb/>](#)
- [Skim these four sample IRB proposals: Mathur example, Nixon example, Salazar example, and Agrawal example](#)

Handouts

- [Interviews](#)
- [Sample interview questionnaires](#)

**Note: Asha has given permission to use language from her IRB application. Great resource, particularly for interview methods!**

## For more info...

San José State University  
**OFFICE OF GRADUATE STUDIES AND RESEARCH**

Home [IRB Requirements](#) [IACUC Requirements](#) [Thesis Requirements](#)  
[Interdisciplinary Studies](#) [Curriculum](#) [Organized Research Units](#) [Funding Opportunities](#)  
GS&R Staff

SJSU Home : Graduate Studies and Research : [IRB Requirements](#)

### Human Subjects - Institutional Review Board

The Institutional Review Board (IRB) is a 10-15 member committee whose task is to review all research conducted by SJSU students, faculty, and staff that involves the use of human subjects, and to make sure that this research is being done in compliance with university policy. The IRB has purview over any research in which people are asked to either participate physically or where information is sought through interviews, surveys, or observation. The IRB also has purview when information concerning individually identifiable people is being sought by a researcher through access to files, data bases, or a third party. Please refer to the links below for information on the required IRB documents, procedures, and IRB related websites.

**General Information**

[IRB Checklist \(pdf\)](#)  
Summarizes all of the documents that need to be submitted for IRB review.

[IRB Procedures \(pdf\)](#)  
An expanded version of the IRB Checklist that summarizes the procedures, timelines, and types of IRB review.

**IRB Forms and Templates**

[Request to Use Human Subjects in Research - IRB Application \(doc\)](#)  
The standard IRB application that must be submitted with all IRB paperwork. Includes: Cover Sheet, Responsible Faculty Member Form, Verification of Transition Accuracy, and Request for extension. Fill out the relevant sections, and type N/A for sections that do not pertain to your application. If more room is needed, please staple a separate sheet to the application.

**Additional IRB Related Resources and External Links:**

- [SJSU Academic Senate](#)
- [US Office for Human Research Protections \(OHRP\)](#)
- [Family Educational Rights and Privacy Act \(FERPA\)](#)

## Important Dates To Remember

- **March 2: Draft IRB Application Due**
- **March 16: Final IRB Application Due**

• Remember, no human subjects research can begin without approval. Avoid delays, turn application in on time 😊

## Image Sources

- <http://www.nature.com/nature/journal/v448/n7153/images/448530a-i1.0.jpg>
- [http://www.sjsu.edu/publicaffairs/pics/patternMotif\\_web.jpg](http://www.sjsu.edu/publicaffairs/pics/patternMotif_web.jpg)
- <http://history.sandiego.edu/cdr2/WW2Pics4/91078.gif>
- [http://www.sjsu.edu/publicaffairs/pics/sjsu\\_logo\\_color\\_web.jpg](http://www.sjsu.edu/publicaffairs/pics/sjsu_logo_color_web.jpg)
- <http://www.let.ru.nl/lcmaster/index.php?id=102>