SAN JOSE STATE UNIVERSITY HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD

IRB Application

Instructions: Prior approval by the Human Subjects Institutional Review Board is required for all research involving human subjects to be conducted by SJSU faculty, students, or staff. Procedures may not begin until approval is received. Students must obtain their faculty supervisor's signature on an <u>assurance</u> form that is included with this application submission; likewise, faculty and staff primary investigators must include the signed assurance form for their research. Please fill out this application completely. Instructions to applicants can be removed prior to submission. Submission instructions appear at the end of this document.

STUDY TITLE

[This title should be consistent with professional practice and clearly indicate the domain of your research and the form of application (evaluation, needs assessment, product or service design, community action).]

FUNDING SOURCE

If the project is not funded, state "no funding. If you plan to apply for an <u>Anthropology GRAD grant</u>, a <u>Vecchi fellowship</u> or a <u>College of Social Science RSCA grant</u>, indicate that here.

ANTICIPATED START DATE

Indicate an approximate date when you want to start the human subjects portion of your research. Make sure the date is not retroactive open submission and allows enough time for the IRB process.

RESEARCH TEAM MEMBERS

Primary Investigator, Student Investigator, or Project Leader

If there is more than one primary investigator or student investigator please identify <u>one</u> point of contact and provide contact information for that individual only. List all other investigators in the "additional study personnel" section below.

Name:	
Email:	
Phone Number:	
Department Name:	

Select One: Faculty Member

□ Staff

Student

Qualifications

Describe any relevant expertise that you or your faculty supervisor (if applicable) have as it relates to this study which prepares you to conduct research with the population identified in the protocol, including relevant coursework, background, experience, and training. Also describe your knowledge of local community attitudes, cultural norms, and the cultural sensitivities necessary to carry out the research, if applicable.

You should list your undergraduate degree, your participation in the Applied Anthropology graduate program, any field or course-based project work you have done, relevant cultural experience and language competency, if relevant.

Additional Study Personnel

List all personnel, including additional primary investigators, who will assist in conducting the research in the table below. If other graduate students or undergraduate assistants are involved, list them here. Add rows as needed:

Name	Role (e.g., Co-PI, research assistant)	List of Responsibilities

EXEMPTION SCREENING

Exemption is not the same as exclusion from review. To determine whether your work is excluded from oversight altogether, please use the <u>Exclusion Worksheet</u> posted on the IRB website.

Exempt status means that the work has been determined to be research that involves human subjects but, if the work meets specific criteria, it does not go through a formal IRB review. Rather, exempt research is registered with the Office of Research. There are still protections in place for the participants, such as the right to be fully informed of the study, and the research is still subject to oversight by the Office of Research. Exempt status is conferred by the Office of Research prior to data collection after the investigator has submitted all of the required supporting documents, including this complete IRB application, consent documents, data instruments, and permission from participating institutions, if applicable.

To help the Office of Research screen your work for exemption, please check all of the boxes below that apply to your research. If you are not sure whether an exemption category applies, leave the box blank.

Some of you in educational anthropology or assessment projects might use exemption (1), others might find (2) relevant. If you are doing interviews or surveys, or public participant-observation, and you record without indicating actual identity, distancing any discussion from the person's identity, or minimal harm—criteria (i) or {ii}—you would be exempt.

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior

(including visual or auditory recording) if <u>at least one</u> of the following criteria is met:

 \boxtimes (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

□ (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review as outlined by federal regulations at 45 CFR 46.111(a)(7).

 \Box (3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and <u>at least one</u> of the following criteria is met:

 \boxtimes (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

☑ **(B)** Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB as outlined by federal regulations at 45 CFR 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

This section could be relevant to those projects designed to elicit user experience.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if <u>at least one</u> of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

□ (5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

These categories are unlikely to relevant to your projects.

STUDY INTRODUCTION

Purpose: Provide an explanation of the purpose of the proposed research written for a general audience. Include a concise statement of your research questions or hypotheses.

In this section it is particularly important to distinguish between a thesis, which may be addressing generalizable questions, and a project that would have a quite specific purpose and audience. Both would have research questions, but the latter would have objectives that serve a limited purpose.

Background: Include a brief (1-2 paragraphs) review of any relevant and current scholarly literature that supports the purpose of the research or that led to the formulation of the study. Include citations and attach a list of references to this submission, if applicable.

This section demonstrates that you know the relevant literature and are prepared to do professional research. It is important to establish that whatever you are doing you are doing it competently, and therefore your research would likely yield benefits that would balance any risk, however small, your research entails.

Research summary: Provide a brief 1 paragraph outline of how you will achieve the study objectives and answer your research questions in the following ways:

Research design (experimental, descriptive, correlational, etc.). You are likely to have a "descriptive ethnographic" or archaeological descriptive and correlational design. What are your research questions? How do your questions support a project goal? What is the relevant literature/research that has already been done on the topic (with citations)? How does your current project add to the body of knowledge? Or serve a client goal? [Not only should you list all your methods, make it clear in this section how they address your research questions. One way is to create a table in which you list your questions, and the corresponding methods for collecting data.

Research Question	Ethnographic method used to collect data pertinent
	to this question

Data collection methods. Are you doing mixed methods, quantitative survey and qualitative observational and interview methods? Are you using existing data sets? *What is the community with which you are working? Who are they and where are they located?*

What methods are you using to get information to address the research questions? (List all such as unstructured conversation, semi-structured ethnographic interview, participant-observation, photographic analysis, textual analysis, archival research, comparative literature research etc.) What is the purpose of your project? If applied, what is the application?

Data analysis methods (describe the specific quantitative or qualitative analyses to be performed, if applicable).

What statistical tests would you use? Make sure they make sense with your sample? What qualitative analytical approaches are you using? How are you massaging your data and presenting it to your client/partner?

PARTICPATING INSTITUTIONS AND LOCATION

- 1. Study location: Where will the study be conducted? List all study sites, including SJSU.
- 2. **Participating institutions**: List any non-SJSU participating institutions that will serve as a source of subjects, a source of records, or a source of information about subjects. Include specific information about the institution's role in your research.
- 3. **Investigator(s) affiliation:** Disclose any affiliation that you have with each study site (e.g., employee, intern, collaborator, client, contractor).

PARTICIPANT POPULATION

Type of subjects: Describe the participant pool or community from which you will enroll participants as specifically as possible (e.g., college students in a specific class, professionals in a specific field, random pedestrians). If you will be accessing secondary data about individuals only, describe whether you are targeting a specific population in your study. If you will have multiple groups of participants, please answer the protocol application questions for all groups. What is the population from which you are sampling? Why is it the appropriate population? Is the intervention or application you are investigating linked to this population? Is this population the logical choice for the research questions you are investigating? How are you sampling this population? Avoid the language of statistical sampling (random etc.), since your project is probably using a nonparametric sample. Who is in, and who is out of the sample and why?

Number of subjects: State the expected number of participants as well as what a reasonable sample size would be to answer your research questions. If applicable, explain how the number of participants needed to answer the research question was determined.

How many people is it reasonable to sample? (The more diverse the sample, the larger it will need to be to reach saturation. While a relatively focused sample can reach ethnographic saturation at 12 people, estimate on the generous side, 15-20, since you do not know what you will find in the field.) If you have internal categories (gender, ethnicity, and economic status), how many in each category will you sample?

Subject demographics: State the age range, gender, and racial or ethnic background of the participant population being targeted, if applicable. Describe the subject population in terms of age, gender, race, ethnicity, etc., including the estimated number of participants.

Inclusion/Exclusion criteria: State any inclusion or exclusion criteria. If prospective participants will be screened via tests, interview, etc., prior to entry into the "main" study, explain how, where, when, and by whom the screening will be done. Information on what will be done with the data of those who do not qualify for the study should also be provided in this section. Explain the rationale for employing the type of subjects selected for the study.

Rationale for subject selection: Describe why this is the appropriate population for your study (i.e., is this population the logical choice for answering your research questions or for applying an intervention?). If applicable, explain why potentially vulnerable participants are needed (e.g., children, pregnant women, economically or educationally disadvantaged individuals, the homeless, the incarcerated, or people with impaired decision making capacity). The chances are good that you are using a maximum diversity sample and if so, what are the categories of diversity you are including (gender, age, family construction, work type, neighborhood location, etc.)? If you are using snowball sampling, unless you are intentionally sampling social networks, how will you avoid bias?

Special needs: Does the subject population have any special needs (do they have limited literacy, will they need translations, etc.)? This is important if you are working with bilingual or monolingual non-English-speakers or another population that needs mediation to communicate.

Prior associations with research team: Are the potential participants already known to the researcher or research team? Have you encountered this population through another project or other means?

POTENTIAL CONFLICTS OF INTEREST

Disclose and address any financial conflicts of interests that any research team member may have as a result of a relationship with the non-SJSU entity financing the research or supplying the materials to be tested under the protocol (e.g., positions of management, equity interest, rights to a pending or issued patent, or licensing rights). You may indicate that there are no conflicts of interest, if applicable. This is a particular issue if you are working on a project through your job. What are the agreements you are making in advance to make sure there are no conflicts of interest?

STUDY PROCEDURES

Recruitment

Recruitment/enrollment procedures: Explain how, where, and when prospective participants will be identified and approached for study participation. Make sure to be clear about how the research team will gain access to participants, what will be said to them, and to outline which members of the research team will conduct the recruitment. If you will be accessing secondary data about individuals only, please describe how you have access to such data and what type of permission you have to access private and protected data (e.g., medical, academic, employment, or financial records). If you will have multiple groups of participants, please answer the questions for all groups. List all means for advertising or outreach. How are you recruiting people to interview? Be specific—if you already have established connections, how will you approach them to help you? Will you advertise, and if so, how? [Include any verbiage you would use to recruit people to participate in your project. Emphasize the voluntary nature of participation and any protections you have planned to prevent any sort of intentional or

unintentional exploitation Also explain your plan to use pseudonyms for people (and vulnerable organizations and places small enough to unintentionally reveal identities), in your publications.]

1. **Potential conflicts of interest:** Do any members of the research team have a supervisory role over potential participants, provide services to the targeted population outside of the research, or serve in a dual role that may result in a power imbalance between researchers and the participants (e.g., teacher/student, employer/employee)?

 \boxtimes NO. Move on to question 3 in this section.

□ YES. Please answer (i) and (ii) below.

(i) Please identify which members of the research team have a supervisory role over potential participants or provide services (such as treatment, assessment, or training) to the targeted population outside of the research, and explain the nature of the relationship to potential participants.

(ii) What precautions will be used to minimize undue influence or potential coercion of participants who are also clients or individuals who receive services from members of the research team outside of the research context?

 Recruitment materials: List any recruitment materials that will be used and note the type of media and where they will be posted. Attach recruitment materials such as telephone or speech scripts, email or letter invitations, flyers or social media postings. Create mockups of all recruitment materials.

Consent Process

The consent process begins with the recruitment of participants, which was described in the previous section. In this section, you will be asked to describe the rest of the informed consent process. If you will have multiple groups of participants, please answer the questions for all groups. If you will be accessing secondary data about individuals only, or if a question does not apply to your study, you may indicate N/A. This section should not be omitted, even if you are doing a low-risk project.

- 1. Who will obtain consent and who will be available to answer participants' questions?
- 2. How will consent be obtained (in person, by email, by mail, via web, signed, unsigned, etc.)?
- 3. Where and when will consent be obtained?
- 4. What language(s) will be used to obtain consent?
- 5. If you anticipate the need to obtain informed consent from a legally authorized representative (LAR) in cases where the subject population under consideration may have impaired decision making ability, describe how you will identify an appropriate representative and ensure that their consent is obtained.

9

Consent Documents

Indicate the type of consent document(s) that will be used. Descriptions of the various types of consent documents are outlined in the <u>Informed Consent Handbook</u> posted on the IRB website. If different consent documents will be used for different participants or methods, check all that apply and indicate which form will be used for which participants/methods. Think about this section carefully. NEVER OMIT CONSENT BECAUSE IT IS INCONVENIENT! There are a few circumstances in which it may be risky or inappropriate.

- □ No consent will be sought
- □ Standard consent form (written consent form, signed by participant)
- □ Parent or guardian permission form
- □ Consent notice (written consent document, unsigned by participant)
- □ Standard consent short form and script (verbal consent only)
- Altered consent form (some of the standard elements of consent are omitted).
 Rationale:

Assent

Minors or adults who have impaired decision making ability should still be informed about the research and asked for their permission to participate, whenever possible, in a manor appropriate to their condition or age. Note: Though consent must be sought first from the LAR or parent before assent is sought, in most social and behavioral research the wishes of the subject override the consent of the LAR or parent. If assent is not applicable to your study, indicate N/A in this section.

- 1. Who will obtain assent and who will be available to answer participants' questions?
- 2. How will assent be obtained in a way that takes into account the age, developmental ability, and cognitive capacity of the subject (e.g., verbal vs. written assent)?
- 3. Where and when will assent be obtained?
- 4. What language(s) will be used to obtain assent?

Assent Documents

Indicate the type of assent document to be used, if applicable. Descriptions of the various types of assent documents are outlined in the <u>Informed Consent Handbook</u> posted on the IRB website. If assent is not applicable to your study, leave this section blank

- □ Assent form (written form, signed by participant)
- □ Assent notice (written form, unsigned by participant)
- □ Assent script (verbal assent only)
- □ No assent will be sought

Rationale (e.g., the capability of the subject to understand the research is too limited, or the research holds out a prospect of direct benefit that is important to the health or well-being of the subject):

What Participants Will Be Asked to Do

If you will be accessing secondary data about individuals only, you may indicate N/A if the question does not apply to your study.

- 1. List procedures in which <u>the participants</u> will take part in a chronological manner. Include only those procedures that involve the participants (e.g., interventions/interactions, data collection procedures). Do not include procedures that the researcher will be doing separately (e.g., literature review, transcribing recordings, data analysis).
- 2. Explain who will conduct the procedures, where and when they will take place. If you be using an online or third party vendor/application to disseminate your data instruments to participants, please provide the name of the online or third party vendor/application.
- 3. Indicate the frequency and duration of each procedure as well as the total time commitment for the study.
- 4. Identify any research procedures, treatments, or interventions that do not conform to commonly accepted clinical or research practice. If the study only involves standard research or clinical procedures, enter N/A here.
- 5. Describe appropriate alternative resources, procedures, or courses of treatment, if any, that are available to prospective participants who choose not to participate or are excluded from the current study.

If the study does not involve a treatment or intervention, enter N/A here.

- 6. Will the study take place in a classroom setting with student participants? Note, this question does not pertain to a lab setting where students may arrive because they have signed up to be part of an experiment.
- \Box NO. Move on to question 7 in this section.
- □ YES. Please answer (i), (ii), and (iii) below.

(i) Explain what activities will be required as part of the normal class activities and what activities will be voluntary as part of the research (be sure to include this information on your consent document).

- (ii) What will students who chose not to participate in the research do?
- (iii) If students will miss class to participate in the research, indicate how they will make up the work.
- 7. Does the study involve deception or providing incomplete information to participants initially?
- \boxtimes NO. Move on to the materials and devices section.
- □ YES. Please answer (i), (ii), (iii) below.
- (i) Explain what the deception or incomplete disclosure will entail (e.g., the consent form will not reveal

complete details about the purpose of the study).

(ii) Explain why the use of deception would fulfill the research purpose better than non-deceptive methods in terms of the study's prospective scientific, educational, or applied value (e.g., deception is needed to minimize biased responses).

(iii) Describe the plans to debrief the participants and include a debriefing script that will be used to explain the deception to participants after their participation or after the study is completed.

Materials and Devices

- List the kinds of data instruments that will be used and attach copies to the protocol (e.g., surveys, questionnaires, interview questions, data intake sheets). We often frame ethnographic questions as conversational guidelines since the questions are not asked verbatim, and should be followed up with prompts and situational queries.
- 2. Describe any cognitive or psychological tests that will be employed and provide representative examples of any computer stimulus or other test materials.
- 3. Will you be using an experimental device (i.e., a device that has not been approved by the FDA or a commercially available device which will be used or investigated in a manner that deviates from the approved labeling)?
 - \Box NO. Move on to question 4 in this section.
 - □ YES. Please answer (i)and (ii) below.

(i) Describe what the device is and how it works. Include diagram(s) and photo(s) of the device that illustrate how it works.

(ii) Is the device a non-significant risk (NSR) device? An NSR device, as defined by the FDA,

is 1) not intended as an implant, 2) not needed for sustaining human life, diagnosing, curing, mitigating, or treating disease, and 3) does not present a potential for serious risk to the health, safety, and welfare of the subject.

- $\hfill\square$ YES. Move on to question 4 below.
- NO. The device poses a significant risk to subjects and requires submission of an application to the FDA in addition to IRB approval. Please contact the SJSU IRB office for more information.

Indicate what types of recording devices will be used to record data from participants by marking all boxes that apply to your study and answering the accompanying questions below. *Ethnographers often use audio and visual recording devices.* At the minimum you are likely to use digital audio recording and notebooks. You might likely use a camera or videorecording device. Make it clear if you are capturing images that undermine anonymity, noting that you are taking photos of spaces, places,

and objects. If you are photographing people, are you doing it in such a way that they cannot be identified? If they can be identified, you cannot claim anonymity and you need additional release of image permissions.]

$\hfill\square$ Standard notetaking on computer or pen and paper

What kinds of information will you be recording in your notes? Describe the kinds of information you will be collecting.

□ Audio recording only

What kind of device will be used? What/whom will you be recording (e.g., individual interview)? Will the recording be transcribed? If so, by whom? Will the transcription contain identifying information about participants? How will the recordings be used? Will the recordings be shared? If so, how and with whom?

$\hfill\square$ Audio and video recording

What kind of device will be used? What/whom will you be recording (e.g., group interview)? Will the recording be transcribed or edited? If so, by whom? Will the transcription or edits contain identifying information about participants? How will the recordings be used? Will the recordings be shared? If so, how and with whom?

□ Photography

What kind of device will be used? What/whom will you be capturing in photographs? How will the photographs be used? Will the photographs be shared? If so, how and with whom? In most cases make it clear you will not capture images of identifiable people.

Other
Please describe:

Data Management Plan

- 1. Will data collected from your data instruments, recording devices, or from secondary sources contain identifying information about participants or contain enough combined information to potentially result in identification of participants? Note image recordings of people are generally considered identifiable unless an obscuring mechanism is built into the recording process.
- \boxtimes NO. Move on to question 2 in this section.
- \Box YES. Please answer (i)-(xi) below. If a question does not apply to your study, write N/A.

(i) What kind of identifying information or potentially identifying information will be collected?

(ii). Will any information that could result in identification of participants be reported with their consent? If so, what kind of identifying information will be reported?

(iii) What mechanisms will be used to maintain the confidentiality of identifying information that participants have not consented to have disclosed (use of a coding system, pseudonyms, etc.)?

(iv) Are you a mandated reporter – someone who is legally required to report abuse, neglect, or a person's intent to harm self or others to the appropriate authority? (If yes, please be sure to also report this limitation to confidentiality on the appropriate consent document if it is applicable to the study).

(v) Are there any other limits to your ability to maintain confidentiality, such as in group interviews and focus groups where you cannot guarantee that participants will not disclose what was shared outside of the group?

(vi) Describe how identifiable data will be transferred (e.g., courier mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe id and how the data will be secured while in transit (e.g., prior encryption).

(vii) How will data containing potentially identifying information be stored and what kind of security features will be in place for the stored data (e.g., password-protected computer or file, encrypted files, locked cabinet)?

(viii) If data are coded in order to retain a link between the data and identifiable information, explain where the key to the code will be stored and how it will be protected.

(ix) Who has access to stored data containing potentially identifying information about participants and who has access to keys for coded data?

(x) What is the retention plan for stored data containing identifying information about participants and what is the retention plan for the key for coded data? How will identifying data be destroyed?

(xi) Will data be shared for use in future research after identifiers are removed? (If yes, please add this information to the appropriate consent document).

- 2. Who is the intended audience for the study report and what is the presentation/reporting method to be used, if known (e.g., journal article, conference presentation)?
- 3. Will aggregate data be shared with the participants after the study is completed? If so, discuss how feedback will be provided to participants.

Compensation

State any compensation that will be provided to participants in the study (e.g., cash payment, gift card, course credit, free treatment). If students will receive extra credit or course credit, state the alternative method(s) that will be available for earning credit for those who do not wish to participate in the research. Note: If your research is funded make sure that the funder allows the form of compensation you wish to provide. If no compensation will be provided, state "none."

Costs

Are there any costs to participants (e.g., transportation to research location, parking expenses, child care)? If the research team will arrange to cover any expenses, mention this here.

BENEFITS

Describe any potential direct benefits to the individual participants or group of participants. If participants will not directly benefit from the study procedures, this should be stated. Note: compensation/payment to participants is not considered a benefit and should not be listed in this section. *These are not benefits to YOU, but benefits to the participant, the participant's community, and disciplinary knowledge. Do not overstate the benefit, but be realistic. Is there a direct positive benefit to the participant, for example, in providing the opportunity for reflection and insight?Is there a direct positive benefit to the participant's community? For example, will your project facilitate better communication between an organization and its client population, or provide data that can inform policies or regulations?Is there an incremental addition to site-specific knowledge to a body of literature within anthropology, of a specific social problem? For example, does your project expand the generalizatibility of a particular theory? Does your project add an anthropological dimension to an interdisciplinary problem or theory?*

RISKS AND RISK MITIGATION

Is there potential personal risk? Are there uncomfortable subjects that could be broached?Are you investigating practices that could be considered embarrassing or illegal?Is your population one that is vulnerable to risk, perhaps due to marginal status, even if they are not in the standard protected categories?Is there potential social risk? Can the community itself be made vulnerable by your investigations? [The risks can range from embarrassment to potential legal vulnerability. Remember, being an anthropologist provides no legal protection should your data be subpoenaed.

- 1. Describe any known potential risks and discomforts to individual participants whether physical, psychological, economic, social, legal, or other and assess their likelihood and seriousness. *Examples of risks include: physical injury, aggravation of an existing condition, pain, loss of privacy, the release of potentially damaging personal information, psychological risk (e.g., anxiety, stress, depression), and uncomfortable emotions (e.g., anger, fear, sadness).*
- 2. Describe the procedures for protecting against or minimizing each potential individual risk listed above. Describe special safety procedures, as needed, to avoid harm to participants. List any psychological and/or medical help available in the event of harm. For example, if the risk of emotional discomfort is high, the investigator should provide the participants with a list of referrals for counseling and attach this information to the informed consent document. [Mitigation can include a range of actions from being empathetic and patient at the time of the interview or observation to providing information on counseling, or carefully editing instances so that they cannot be associated with an individual]
- 3. Describe if there are plans for provision of treatment for study-related injuries and how costs of injury treatment will be covered.

- 4. Describe if there is an indirect risk of group harm (i.e., can the community from which participants are selected be made vulnerable by the investigation?).
- 5. Describe the procedures for mitigating group harm (e.g., community consultation, identifying stakeholders as mediators).

OTHER

If there are any other issues which should be considered and which do not fall into any category above, please describe them here.

ATTACHMENTS

Attach all of the documents listed, if applicable. Please be sure to label each document in the upper right hand corner so that the IRB can easily identify what type of document it is.

- A signed primary investigator or faculty supervisor assurance form
- Recruitment materials (and translations)
- Consent and assent documents (and translations, if applicable)
- Data instruments (and translations, if applicable)
- Translation accuracy verification form, if applicable
- Permissions from institutions/letters of support
- Current faculty training certificate (if not previously submitted)
- List of references

SUBMISSION INSTRUCTIONS: Please email this application, along with your other attachments to irb@sjsu.edu. Allow 3-5 business days for pre-review and email confirmation from the IRB analyst.