**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* [*assurance*](http://www.sjsu.edu/research/docs/irb-assurance.pdf) *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. Italicized Instructions to applicants can be removed prior to submission, but please keep page numbering for easy reference. Submission instructions appear at the end of this document.*

**SECTION I – BASIC STUDY INFORMATION AND PERSONNEL**

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STUDY TITLE**

**FUNDING SOURCE***If the project is not funded, state “no funding.”*

**ANTICPATED 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 one 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.*

**Additional Study Personnel***List all personnel who will assist in conducting the research in the table below. Add rows as needed:*

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Role** (e.g., Co-PI, research assistant) | **Affiliation** (i.e., SJSU Faculty, SJSU Student, SJSU Staff, or External) | **List of Responsibilities** |
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**SECTION II - EXEMPTION SCREENING  
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*Exemption is not the same as exclusion from review. To determine whether your work is excluded from oversight altogether, please use the* [*Exclusion Worksheet*](http://www.sjsu.edu/research/docs/irb-exclusion-worksheet.pdf) *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.*

**(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 at least one of the following criteria is met:

**(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).  
  
 **(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 at least one of the following criteria is met:

**(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 review 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.

(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 at least one 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.

**SECTION III - STUDY INTRODUCTION  
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**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.

**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 include a list of references in this submission, if applicable.

**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:

1. Research design (experimental, descriptive, correlational, etc.).
2. Data collection methods.
3. Data analysis methods (describe the specific quantitative or qualitative analyses to be performed, if applicable).

**SECTION IV - PARTICPATING INSTITUTIONS AND LOCATION  
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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).

**SECTION V - PARTICIPANT POPULATION  
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1. **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.
2. **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.
3. **Subject demographics:** State the age range, gender, and racial or ethnic background of the participant population being targeted, if applicable.
4. **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.
5. **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).
6. **Special needs:** Does the subject population have any special needs (do they have limited literacy, will they need translations, etc.)?
7. **Prior associations with research team*:***Are the potential participants already known to the researcher or research team?

**SECTION VI - POTENTIAL FINANCIAL CONFLICTS OF INTEREST   
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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.

**SECTION VII - STUDY PROCEDURES  
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**Recruitment**

1. **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.
2. **Potential interpersonal 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)?   
    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?

1. **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.

**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.*

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.**

**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* [*Informed Consent Handbook*](http://www.sjsu.edu/research/docs/irb-consent-handbook.pdf) *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.*

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). Note: this option should only be used if participants have limited literacy or are otherwise unable to read a consent document.

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 manner 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 or omit the 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* [*Informed Consent Handbook*](http://www.sjsu.edu/research/docs/irb-consent-handbook.pdf) *posted on the IRB website. If assent is not applicable to your study, leave this section blank or delete it.*

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 the participants 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 will be using an online or third party, vendor, or 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.*

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 choose 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.

1. **Does the study involve deception or providing incomplete information to participants initially?**

NO. Move on to Section VIII – Materials and Devices.  
 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 or incomplete disclosure 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 or incomplete disclosure to participants after their participation or after the study is completed.

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

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.

1. **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.**

**Standard note-taking on computer or pen and paper**What kinds of information will you be recording in your notes?

**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 or potentially identifying information about participants? How will the recordings be used? Will the recordings be shared? If so, how and with whom?

**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 or potentially 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?

**Other**Please describe:

**SECTION IX - DATA MANAGEMENT PLAN  
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*To understand your basic data management obligations please refer to the IRB’s*[*Data Management Plan Checklist*](http://www.sjsu.edu/research/docs/irb-data-management-checklist.pdf)*. For more comprehensive information about data management, please refer to our* [*Data Management Handbook*](http://www.sjsu.edu/research/docs/irb-data-management-handbook.pdf)*, which expands on topics covered on the checklist and provides a glossary of terms. To help you prepare your responses to questions in this section, we recommend using our* [*Excel Data Management Plan Template*](http://www.sjsu.edu/research/docs/irb-data-management-plan-template.xlsx)*, a tool for mapping and keeping track of important data elements throughout your research. You are not required to submit the Excel spreadsheet with your application. However, the IRB may request that you use the spreadsheet if your responses to the below questions are unclear.*

1. **Data Inventory**

*Please respond to the questions in this part using complete sentences rather than N/A. If you indicate under (i) and (ii) that no direct or indirect identifying information will be collected or known to the research team, you may skip questions 2-5 and move on to section X of this application. Note: asking participants to sign a consent form means that you will collect direct identifying information.*

(i) What kind of direct identifying information will be known to the research team or collected from participants (e.g., name, email address, phone number, ID, biometric info, images, certain metadata)?

(ii) What kind of indirect identifying information will be collected that, when combined, could reasonably result in the identification of participants (e.g., gender, racial or ethnic identity, age, location information, certain metadata)?

(iii) Do any of the data elements that you plan to collect fall into Level 1 or 2 of the [SJSU Information Classification Scheme](http://www.sjsu.edu/it/docs/security/policies-standards/Cheat_Sheet_Information_Classification.pdf)? If so, which data elements?

(iv) What is the intended research use for the direct and indirect identifying information?

1. **Storage, Security, and Safeguards**

(i) Please indicate the format of data you plan to collect that will contain direct or indirect identifiers (check one):

Digital only  Paper only  Both digital and paper

(ii) Where will digital files containing direct or indirect identifiers be stored and what specific devices will be used for storage? Describe any personal device(s), institutional device(s), institutional shared drive(s), etc., and identify the data elements to be stored on each. If data will be stored on portable devices (phones, memory sticks), please also explain where the portable devices will be stored when not in use.

(iii) What kind of security features (physical and/or technical safeguards) will be in place for each of the files, devices, cloud-based locations, or papers where direct or indirect identifying information will be stored?

(iv) If you will de-identify data, please explain the method and timing of your de-identification procedures.

(v) 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. Likewise, if you will be storing consent forms separately from the data, please state where each will be stored.

(vi) Explain if and how identifiable data will be transferred (e.g., courier mail) or transmitted (e.g., file transfer software, cloud-based file sharing, email). If transmitted via electronic networks, describe if and how the data will be secured while in transit (e.g., encryption). If you will be traveling internationally with identifying information, describe any additional security protocols that will be in place for your devices.

1. **Access**

(i) Which of the team members listed in the personnel section of this application will have access to identifying information about participants? If applicable, list the identifying data elements that each team member will have access to, as well as which team member will be given passwords, coding keys, and other access tools.

(ii) Will team members who have access to identifying information receive training, and what kind of training will be offered (e.g., CITI training modules, CSU Learn, research-specific instructions created by the PI)?

(iii) Will access to identifying information be granted to individuals, institutions, or vendors who are not part of the research team? If so, please identify who else will have access, the rationale for providing the access, how access will be provided, and what steps will be in place to ensure proper handling of the identifying information by third parties.

1. **Dissemination**

(i) Will any information that could result in identification of participants be reported in the research findings? If so, what kind of identifying information will be reported and will participants be informed of this?

(ii) 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.)?

(iii) Are you or any of the research personnel 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 only if it is applicable to the study).

(iv) Are there any other limits to your ability to maintain confidentiality, such as in group interviews, where you cannot guarantee that participants will not disclose what was shared outside of the group? (Repeat on the consent form).

(v) Will data be shared for use in future research? If yes, please describe what data elements will be retained and shared for future research and add this information to the appropriate consent document.

(vi) 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)?

(vii) Will data or research findings be shared with any participating institutions from which subjects were recruited (for example, to school administrators at a secondary school where students were recruited)?

(viii) Will aggregate data be shared with the participants after the study is completed? If so, discuss how feedback will be provided to participants.

1. **Retention and Disposition**

(i) How long will identifying information and/or keys to coded data be kept? Note: this question refers to identifying information and not all research data.

(ii) How will identifying information be destroyed when it is no longer needed? Please list the specific disposition methods for various media, including paper documents, digital documents on devices, and digital documents on shared drives, in the cloud, or email.

(iii) Who will conduct the disposition/destruction of identifying information?

**SECTION X – COMPENSATION AND COSTS  
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1. **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.”*
2. **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.**

**SECTION XI – BENEFITS  
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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.*

**SECTION XII - RISKS AND RISK MITIGATION  
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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.
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).**

**SECTION XIII – OTHER  
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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. **If you have multiple attachments, please be sure to label each document in the upper left hand corner so that the IRB can easily identify what type of document it is.**

* A signed primary investigator or faculty supervisor [assurance form](http://www.sjsu.edu/research/docs/irb-assurance.pdf)
* Recruitment materials (and translations, if applicable)
* 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](mailto:irb@sjsu.edu). Allow 3-5 business days for pre-review and email confirmation from the IRB analyst.