## 1. PROJECT REVIEW:

Please note, this is template to help you prepare your IRB application but you will still need to submit everything through the online Cayuse system.

All Investigators and research assistants involved with a protocol MUST complete the CITI Course in Human Subjects Online Training before submitting an IRB application (see the policy at <https://www.csusb.edu/institutional-review-board>). Please attach a digital file of your CITI Training Completion Report with the IRB Application by uploading the report(s) to Section 2.

Note: Regarding the online IRB application system (Cayuse IRB). CSUSB faculty and students must be inputted into the Cayuse IRB system. Once inputted, faculty and student(s) will have direct access to the online application. Use the People Finder tool, which allows you to search for faculty and/or students by inputting their names, to automatically populate the investigator(s)/researcher(s) information into the IRB application. You can enter multiple faculty members if more than one investigator is involved in the research study. Off-campus researchers unaffiliated with CSUSB do not have access to this application.

**Select the appropriate reviewers for your study. Please select one only.**

1. Main IRB Committee - Reviews exempt (administrative), expedited, and full board review applications
2. Department of Psychology Designated Primary Reviewers - Reviews exempt (administrative) and expedited review applications only
3. School of Social Work Designated Primary Reviewers - Reviews exempt (administrative) and expedited review applications only

**Note:** The System will automatically assign you an IRB number

* Main IRB Committee
* Department of Psychology Designated IRB Reviewers
* School of Social Work Designated IRB Reviewers

## 2. INVESTIGATOR(S):

The principal investigator (PI) in most cases is the person conducting the study (e.g., faculty, staff, or administrators).

### PI (Principial Investigator) on Research Study

**\****The PI must be the CSUSB faculty or full-time staff member who has primary responsibility for the study***.**

\_\_\_\_(Enter contact info; college or university affiliation, address, phone number, email)

### Co-Principal Investigator(s): Enter only CSUSB investigators here including students, faculty, and staff.

\_\_\_\_(Enter contact; college or university affiliation, address, phone number, email)

Primary Contact

\**Primary Contact for this study (may be the same as the PI):*

\_\_\_\_(Enter contact info; college or university affiliation, address, phone number, email)

\*Please check the appropriate box to indicate whether the Principal Investigator (PI) is faculty, student, staff, and others.

* Faculty
* Staff
* Other

The text box area below can be used for the following:

Add Non-CSUSB affiliated investigators and/or key personnel such as evaluators, external investigators as needed. If CSUSB students don't populate in the above co-PI section, please add them below in the text box.  Please include their first and last name and contact information (email address, phone number, and institutional affiliations for each additional key personnel).

Reminder: Non-CSUSB affiliated investigators may only be added in the text box area as they cannot be added to the Cayuse IRB system.

|  |
| --- |
|  |

Student(s): Please indicated if this research study is for your dissertation, thesis, independent study, project, course, or other (if you selected other please include a description below as needed).

Faculty: Please select if this research study is for a course, research study, or other (if you selected other please include a description for needed below).

 \_\_\_ Faculty Research Project

 \_\_\_ Course

 \_\_\_ Doctoral Dissertation (Ed. D)

 \_\_\_ Graduate Thesis (Master's)

 \_\_\_ Independent Study

 \_\_\_ Social Work Project

 \_\_\_ MBA/MPA Project

 \_\_\_ Cooperative Research Agreement

 \_\_\_ Certification of Data Set

 \_\_\_ Other

\*Human Subjects Training completion reports must be included for ALL investigators and other personnel involved in the study (e.g., faculty advisers, students, principal investigators, co-principal investigators, key personnel, and evaluators).

\_\_\_ Please attach CITI Online Human Subjects Training Completion Report(s) below.

## 3. DATA COLLECTION:

\*Enter the proposed start date of your study allowing sufficient time for the IRB to review your application

**Exempt (Administrative) or Expedited Review**

The study start date should be at least 30 days from the day you submit your IRB application.

**Full Board Review**

* The study start date should be at least 45 days from the day you submit your IRB application.

Note: **Regardless of the estimated start date, protocol approval periods are valid for 1 year concurrent with the date the protocol was approved**

Proposed Start Date of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Indicate the number of participants proposed for your study: \_\_\_\_\_\_\_\_

Demographic Information:

\_\_\_ Female

\_\_\_ Male

\_\_\_ Other (for participants that do not identify as male or female)

Specify the type of participants you plan to use:

\_\_\_ Adults (18 years of age or older)

\_\_\_ Children (17 or younger)

\_\_\_ CSUSB students

\_\_\_ Child Development Center

\_\_\_ Faculty or external reviewers

\_\_\_ Patients in institutions

\_\_\_ Pregnant women

\_\_\_ Prisoners

\_\_\_ Other

## 4. FUNDING:

Grant Funding Questions

Note: Funding refers to internal or external grants specific to the research, NOT professional development funds. If using professional development funds for the research please indicate "I am not seeking funding".

\_\_\_ I am not seeking funding

\_\_\_ I am seeking funding

\* Please indicate the type of grant funding you are seeking

\_\_\_ Internal (Funding from CSUSB)

\_\_\_ External (Funding from organizations/agencies outside the University)-

\_\_\_ I already have funding

\* Please indicate the type of grant funding you possess

\_\_\_ Internal (Funding from CSUSB)

\_\_\_ External (Funding from organizations/agencies outside the University).

Please attach funding award letter -

## 5. REVIEW TYPE:

Please note the following:

* The IRB will make the final determination if the category or categories of review you selected are appropriate and will notify the researcher(s) of its decision.
* The IRB may determine that your study is not research (i.e., does not fall under the federal definition of research) and issue you a Not Human Subjects Research (NHSR) letter.
* The following are the revised common rule exempt categories effective January 21, 2019. Source: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html>

### \_\_\_ Non-Human Subjects Research (NHSR)

The NHSR form can be found at the following webpage under [IRB Forms](https://www.csusb.edu/institutional-review-board/irb-review/forms-and-templates)

The CSUSB IRB is required under federal regulations to review and approve all research involving human subjects. The following sections will help you independently determine whether your investigation is a case of **Human Subjects Research** or **Non-Human Subjects Research**
**(NHSR)**.

If your investigation meets the definition of human subjects research, you are required to submit a full IRB protocol for exempt, expedited, or full board review through the [online application](https://www.csusb.edu/institutional-review-board/irb-application-forms-and-submission-system) system.

If the proposed activity does not meet the definition of human subjects research, your investigation does not need to be reviewed or approved by the IRB. However, if you need documentation from the CSUSB IRB stating that your activity is not research and/or does not involve human subjects, please submit an [online application](https://www.csusb.edu/institutional-review-board/irb-application-forms-and-submission-system) (see Section 3 below for more details).

For further questions, please contact mgillesp@csusb.edu or irb@csusb.edu

**\* Please answer the questions below for the IRB to determine your study NHSR.**

**SECTION 1: DETERMINATION OF "HUMAN SUBJECTS RESEARCH":**

**PART A: RESEARCH**
First, determine if your investigation is a form of "research" under the definitions of PART A: 45 CFR 46.102:
Research -- a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

A systematic approach involves a predetermined system, method, or plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory. A systematic approach includes the collection of information and/or biospecimens, and analysis either quantitative or
qualitative.

Activities designed to develop or contribute to generalizable knowledge are those activities designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable).

**The following activities are deemed not to be research under the 2018 Common Requirements

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

If you believe you meet the non-human subjects research requirements, you do not need to complete sections 6 - 12 on the left side of the (online) application.**

\_\_\_\_ Attach NHSR Form.

The NHSR form can be found at the following webpage under [IRB Forms](https://www.csusb.edu/institutional-review-board/irb-review/forms-and-templates)

\*<<For human subjects research>>\* Read each review type section below and indicate which category your research falls under. If you open a section and none of the categories apply to you close the section and move on to the next review type section.

Students Should work with their Faculty Advisor to determine which review type and category is most appropriate.

**NOTE: If you open a review type section where none of the categories apply to your research and continue working on the application with the review type section open you will not be able to submit the application until the section has been closed.**

### \_\_\_ Administrative (Exempt) Review:

Studies containing no risk or less than minimal risk

**Exempt Categories: Check the appropriate box(es) that apply to your study, if none of these categories apply to your research close this review type section and move on to Expedited Review.**

**Note: More than one category type may apply to your protocol, so please check all category boxes that apply to your protocol.**

 **\_\_\_ Exempt Category 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.

**\_\_\_ Exempt Category 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 to make the determination required by  46.111(a)(7).

**\_\_\_ Exempt Category 3:**

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 IRB review to make the determination required by 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.

**\_\_\_ Exempt Category 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.

**\_\_\_ Exempt Category 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.

**\_\_\_ Exempt Category 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.

**\_\_\_ Exempt Category 7:**

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 46.

**\_\_\_ Exempt Category 8**

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

### \_\_\_ Expedited Review:

Studies possessing no more than minimal risk

**Expedited Review Applicability: Please check the appropriate box(es) that apply to you study, if none of these categories apply to your research close this review type section and move on to Expedited Review.

Note: More than one category type may apply to your protocol, so please check all category boxes that apply to your protocol**

**\_\_\_ Expedited Category 1**

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

1. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.

2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling

**\_\_\_ Expedited Category 2**

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week;

or

b) from other adults and children [[2]](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/#footnote2), considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

**\_\_\_ Expedited Category 3**

Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

**\_\_\_ Expedited Category 4**

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

**\_\_\_ Expedited Category 5**

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.[45 CFR 46.101(b)(4)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). This listing refers only to research that is not exempt

**\_\_\_ Expedited Category 6**

Collection of data from voice, video, digital, or image recordings made for research purposes

**\_\_\_ Expedited Category 7**

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.[45 CFR 46.101(b)(2)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) and (b)(3). This listing refers only to research that is not exempt).

**\_\_\_ Expedited Category 8**

Continuing review of research previously approved by the convened IRB as follows

a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

. b. where no subjects have been enrolled and no additional risks have been identified; or

c. where the remaining research activities are limited to data analysis.

### \_\_\_ Full Board Review:

More than minimal risk studies.

## 6. PROJECT DESCRIPTION:

Please answer the questions below as clearly and accurately as possible.

#### A. Objectives of the Study: (Recommended length 1 paragraph).

Insert text here:

#### B Background Theory and/or Literature Review. Please be concise so reviewers can evaluate the merit of the study.

Insert text here:

#### C. Hypothesis or Research Questions.

Insert text here:

#### D. Recruitment & Data Collection:

First, describe how you plan to recruit or sample participants (who, where, when, how long, how, through what means, etc.). Second, describe, how data related to human subjects will be collected (where, when, how long, how, through what means, etc.).

For recruitment materials please include the following:

* + Name and contact information of the principal investigator and/or research facility;
* A concise description of the purpose of the research;
* Eligibility criteria for participant participation;
* Time or other commitment required of the participants;
* Location of the research and person to contact for further information; and
* A statement saying, “This study has been approved by the CSUSB IRB” (including the IRB # is recommended)

Insert text here:

#### E. Methodology (not mentioned in section D) and Data Analysis: Briefly describe how you will organize and analyze data collected.

Insert text here:

F. COVID-19 Related Questions (Optional)

The IRBs goal is, as always to decrease risk to human participants when at all possible. We recommend that researchers continue to refer to CSUSB campus policy, CDC, and local guidelines related to COVID-19, as they can continue to change. As of May 23, 2022, CSUSB IRB no longer requires new applications to include COVID-19 protocols.

**However, if you have high risk participants (as defined by**[**CDC**](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html)**), you should answer the following COVID-19 safety protocols:**

What specific health risk related to COVID-19 do you anticipate participants would be exposed to when participating in your research, and what measures (see list below) will be taken to reduce these identified health risks during the research process?

* Social distancing
* Contact tracing
* Screening
* Cleaning
* Masking and/or personal protective equipment
* Ventilation (indoor/outdoor)
* Other measures related to your specific participants

Insert text here:

#### G. Dissemination:

Describe how you will present and/or publish your research. For example: Will you present your research at a conference, publish in a scholarly journal, report in your thesis, or report in your dissertation?  Insert text here

**\*Attach recruitment materials and approvals here.**

**MATERIALS**:

Flyers, Advertisements, e-mails, etc.

**APPROVALS:**

Add letters of approval/permission on letterhead from cooperating agencies, boards of education, school districts, businesses, hospitals, and other agencies and groups

**Note: All flyers or materials regarding participant recruitment are required to state, "This study has been approved by the California State University, San Bernardino Institutional Review Board" and**MUST **be on department letterhead.**

**\_\_\_\_ Attach instructions, surveys, questionnaires, interviews, and measurement instruments given to participants here:**

## 7. CONFIDENTIALITY:

In this section, explain the how, what, when, and where you will store and secure the data you have collected. Clearly indicate specific procedures (e.g., coding of responses, aggregate reporting) to protect the confidentiality of participants and safeguard identifiable records and data. This includes safe and secure storage of the collected information and when the data will be destroyed after the data collection process has been completed (if applicable). If not possible, state why.

If collecting your data through interviews or focus groups, be specific as to the type of recordings (i.e., audio, video, photograph) and type of recording devices used (i.e., analog or digital). If transferring from any files (digital/tape recordings) how will you transcribe the data and what will you do with the recordings after transcription? If you are destroying recordings, please include how you will destroy them after transcription (e.g., demagnetize, shred)?

If digital recordings are used, how will you be transferring the data from the digital recording device to a computer, and what will be done with the data on the digital recording device after you have downloaded the data to the computer (e.g., data will be erased, deleted, overwritten)? See[CSUSB Safeguarding Confidential Information Standards.](https://www.csusb.edu/sites/default/files/CSUSB%20Safeguarding%20Confidential%20Information_011421.pdf)

**Note: A common mistake individuals make is misinterpreting confidentiality versus anonymity. For reference: Anonymous data is data recorded so that the information can never be linked to the participant who supplied it. Confidential data is data collected in a way that the participant could be identified from the data.**

Insert text here:

## 8. RISKS AND BENEFITS:

Risks

Describe in detail any immediate, short-term, or long-range risks that may arise for participants as a result of procedures associated with your study. Risks may be physical, psychological, social, legal, or economic; they would include side effects, delay in customary treatment, social or psychological discomfort, etc. Indicate any precautions that will be taken to minimize risks. Risks and benefits **MUST BE** included in the protocol and in the informed consent document. Insert text here:

Benefits

Describe any anticipated benefits to participants and/or society from the knowledge that may reasonably be expected to result from the study. If the research study is considered more than minimal risk to participants, please explain how your research team will minimize risk to participants (e.g. investigators hold specific certification(s), previous experience with a specific population, previous experience in research with high-risk studies, presence of medical staff, counseling resources, local medical facility resources, debriefing procedures). Insert text here.

**Note: Please note that any compensation granted to the participant is NOT a benefit of the study; it is an incentive.**

Incentives

Please include any incentives you propose to provide the participants below. Describe who will be eligible for these incentives and how those incentives will be delivered. . Insert text here:

Note: Please be aware if your research plans to provide incentives to CSUSB student and faculty participants, please note the IRS regulations on reporting incentive payment. The Internal Revenue Service (IRS) requires study participant payments aggregating $600 or more paid to an individual during a calendar year to be reported on IRS Form 1099-MISC, Miscellaneous Income. This is not necessarily an IRB issue, but please work with the university to clarify the procedures.
<https://www.irs.gov/pub/irs-pdf/i1099mec.pdf>The Office of Student Research (OSR) has guidelines for issuing Gift Cards to student research participants.
[https://www.csusb.edu/student-research/resources/g...](https://www.csusb.edu/student-research/resources/gift-cards)

## 9. INFORMED CONSENT & COI/FCOI:

Informed consent is generally in written format. However, in some circumstances, it may be oral or electronic in nature. Remember that the informed consent should be unique to each study being proposed and should also be written at the 6th to 8th-grade reading level or lower if needed. (An example of an informed consent format is provided on the IRB website. You do not have to follow the example format, but it must include the federally required sections below in items 1 through 9.

Waivers of informed consent may be granted under certain limited conditions, and any request for such should include an explicit justification ([Waiver of Consent Criteria](https://www.csusb.edu/institutional-review-board/irb-review/forms-and-templates))

For an example Informed Consent please refer to the CSUSB IRB website or click on the following link: [Informed Consent Example](https://www.csusb.edu/sites/csusb/files/EXAMPLEINFORMEDCONSENT12-12-13.doc)

The IRB requires a text of the proposed statement to be used for oral or electronic consent. Like written consent, they should include:

A statement that the research has been approved by the Institutional Review Board of California State University, San Bernardino (should be in the first paragraph)

1. Identification of the researcher(s)
2. The nature and purpose of the study
3. Expected duration of participant involvement
4. How confidentiality or anonymity will be maintained
5. The voluntary nature of participation
6. Participants right to withdraw at any time without penalty
7. Information about foreseeable risks and benefits (or none)
8. Contact information for questions or additional information

The informed consent or text for oral consent must be provided to the IRB as an attachment (below) and should appear on the faculty member's/faculty adviser's office letterhead.  If you are a student, your faculty advisor may be able to provide you with their office letterhead in a digital (electronic) format so you can cut and paste your consent document onto the letterhead.  For non-English-speaking participants, be sure to include the translation in the appropriate language of the participants.

A common mistake individuals make is misinterpreting confidentiality for anonymity.  For reference purposes please note the following:

Anonymous data is data recorded in such a manner where the information can never be linked to the participant who provided it.

Confidential data is data collected in a way that the participant could be identified from the data collected.

**\_\_\_ Attach your Informed Consent here.**

It is recommended the informed consent be included on your department letterhead. If you're a student researcher, this would be your faculty adviser's department letterhead. General rules:

* Studies approved under expedited and full board review require a signed consent document unless waived by the IRB.
* Studies determined exempt do not require a signed consent (For example anonymous surveys distributed in person or online and do not need to be on department letterhead. The CSUSB IRB still requires investigators to obtain consent for studies determined exempt.

### Requesting Waiver of Consent

Under federal regulations, a researcher may request a waiver of consent under certain conditions. Please visit the websites below for more information. There are generally two types of waiver of consent.

1. General waiver or alteration of consent: Visit and review regulations at  [46.116 (f)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116).
2. General waiver of documentation of informed consent. Visit and review regulations at [46.117 (c) (1)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117).

Please visit the websites above for information on requesting a waiver of consent. Researchers use the text area below to justify your request for a waiver of consent.

 Inert text here

### Conflicts of Interest (COI):

Conflict of Interest Questions:

Federal regulations require investigators to disclose any conflicts of interests (COI) in research they may have related to the IRB application. The term “conflict of interest in research” refers to situations in which financial or other personal considerations may compromise or have the appearance of compromising a researcher's professional judgment in conducting or reporting research. COIs/FCOIs must be disclosed to participants in the informed consent.

Insert text here:

## 10. CHILD ASSENT:

Assent is defined by the regulations as follows: Assent means a child's affirmative agreement to participate in research. Mere failure to object (i.e., absent of affirmative agreement) should not be construed as assent. (See federal regulation at [45 CFR 46.402 (b)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402)).

The child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the Institutional Review Board (IRB) is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge the child's capacity to assent for all the children involved in proposed research activity, or on an individual basis. A child assent example is provided on the IRB website under the IRB Application, Forms and Submission menu tap.

For an example Assent form please refer to the CSUSB IRB website or click the following link: [Child Assent Form Example](https://www.csusb.edu/sites/csusb/files/child_assent_example.doc)

**Provide the child assent form as a written text (in the box below) and as an attachment (below).**

\_\_\_ Attach your Child Assent form here.

**Note:**If applicable, assent forms should be on the department letter.

## 11. DEBRIEFING:

A debriefing statement is usually required only if any type of deception is used in the study. Participants may also be debriefed about their behavioral response(s) to the study. The two major goals of debriefing are de-hoaxing and de-sensitizing. Any undesirable influence the study may have on participants should be minimized or eliminated.

The debriefing statement should describe the reason(s) for conducting the research, how participants can obtain results of the study and contact information for additional details or answers to questions. It would also be advisable, for methodological purposes, to request that participants not reveal the nature of the study to other potential participants. If you are a student researcher please check with your faculty advisor on whether you should include a debriefing statement.

Some researchers use an information form at the end of their studies to include relevant follow-up contact information of the faculty or student investigator(s). This may also include additional information for counseling services or emergency hotline numbers for those experiencing distress after a research/study procedure has ended and results in the participant recalling past instances of psychological or physical trauma. You may include an information or emergency contact form (so titled) if needed but please refer to your faculty advisor if you are a student researcher.

For an example debriefing form please refer to the CSUSB IRB website or click the following link: [Debriefing Form Example](https://www.csusb.edu/sites/csusb/files/SAMPLE%20Debriefing%20Statement.doc)

**Provide your debriefing statement as a written text (in the box below) and as an attachment (below).**

\_\_\_ Attach your debriefing form/statement here.

## 12. OTHER ATTACHMENT:

Please provide any other attachments necessary for your study that have not been previously requested.

--- END OF APPLICATION TEMPLATE. PLEASE ENTER YOUR ANSWERS ONLINE--