CSUSB IRB Initial Submission

**TEMPLATE ONLY**

*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.*

**Last update:** June 28, 2024

# 1. PROJECT REVIEW

Before proceeding with this IRB application, please note the following:

1. **For all applicants**: Complete the CITI Course in Human Subjects Online Training for all persons listed in this application (see **instructions** [here](https://www.csusb.edu/institutional-review-board/human-subjects-ethics-training).) Please attach PDF files of CITI Training Completion in Section 2 INVESTIGATORS.
2. **For student researchers** (for dissertation, thesis, projects, presentations, etc.)**:** Please do *not* certify or submit the IRB application unless your faculty advisor has reviewed and edited this.

* Faculty advisor must be both the primary contact and the PI (Principal Investigator) in this application. The student will be a Co-Principal Investigator. See Section 2 INVESTIGATORS for more information.

\* required

Below, please SELECT the appropriate REVIEWERS for your study. Please select ONE committee ONLY:

**Main IRB Committee** -- For most departments and offices, check here for Exempt (administrative), Expedited, or Full Board review applications.

**Department of Psychology Designated Primary Reviewers** -- For psychology faculty and students only, check here for Exempt (administrative) or Expedited review applications only. (Please select Main IRB committee above if this is for Full Board review.)

**School of Social Work Designated Primary Reviewers** -- For social work faculty and students only, check here for Exempt (administrative) or Expedited review applications only. (Please select Main IRB committee above if this is for Full Board review.)

# 2. INVESTIGATORS

**For Student Research (thesis, dissertation, projects), please follow these steps closely:**

1. Add the faculty advisor as the Principal Investigator (PI).
2. Add the student as Co-Principal Investigator (Co-PI).
3. Add the faculty advisor as the Primary Contact.

* **Important:** If you made a mistake on the primary contact, please make sure the student investigator is first listed as the Co-PI *before* changing the Primary Contact. If the student investigator is first removed from the Primary Contact, the student investigator will no longer have access to the application. If this does happen, the faculty advisor (PI) needs to add the student back onto the application as the Co-PI.

**For all:**

1. The Principal Investigator (PI) in most cases is the person conducting the study (e.g., faculty, staff, or administrators). Faculty advisors will be the PIs for student research.
2. You may add CSUSB affiliated personnel in the Co-Principal Investigators section.
3. For non-CSUSB affiliated personnels (e.g., evaluators, recruiters, etc.), please add contact information in the Non-CSUSB Investigators box below.

## INVESTIGATORS' INFORMATION

Please enter the appropriate information below:

\*required

#### **PI (Principal Investigator)**

The PI must be the CSUSB faculty or full-time staff member who has primary responsibility for the study. For student research, the faculty advisor must be the PI. Click "FIND PEOPLE" and enter your name, select the plus sign. This adds you as the PI.

* Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Organization: \_\_\_\_\_\_\_\_\_\_\_\_
* Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

#### **Co-Principal Investigator(s):**

1. For student honors/thesis/dissertation/projects, the student must be listed as the Co-PI. Students may add additional faculty as Co-PIs here, as needed.
2. You may enter more than one Co-PI if needed.
3. Use "FIND PEOPLE" below to select the Co-PI. Enter your name and select the plus sign to add the Co-PI. If you cannot find the names in the "Find People" directory, or if other investigators are not associated with CSUSB please enter their information below in the "Non-CSUSB affiliated" box.

* Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Organization: \_\_\_\_\_\_\_\_\_\_\_\_
* Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

#### **PRIMARY CONTACT**

\*required

**Primary Contact**

Important: The Primary Contact must be the same as the PI (Principal Investigator). Follow the same procedures using the People Finder Function by entering the PI’s name and select the plus sign to add the PI as the primary contact.

* Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Organization: \_\_\_\_\_\_\_\_\_\_
* Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please check the appropriate box to indicate whether the Principal Investigator (PI) is a faculty member, staff member, administrator, or other personnel in CSUSB.

Faculty

Staff Administrator Other

#### **NON-CSUSB INVESTIGATORS**

Add Non-CSUSB affiliated investigators and/or key personnel such as evaluators, external investigators as needed.

Please include the following information for each personnel:

* First and last name;
* Contact information (email address, phone number);
* Institutional affiliation.
* Please indicate their roles in this research.

\*\* If CSUSB members don't populate the above Co-PI section, please add their information in this area.

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\*required

### **RESEARCH TYPE:**

**Student(s):** Please indicate if this research study is for your dissertation, thesis, independent study, project, course, or other purposes (if you selected Other, please include a description).

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

Faculty Research Project

Researching a course/teaching (for faculty only) Doctoral Dissertation (Ed.D.)

Master's Thesis/Project Independent Study/Honor's Project

Social Work Thesis/Project MBA/MPA Thesis/Project Cooperative Research Agreement Certification of Data Set

Other (Please explain): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*required

### **CITI TRAINING CERTIFICATES**

ALL investigators and other personnel involved in the study (e.g., faculty advisers, students, principal investigators, co-principal investigators, key personnel, and evaluators) MUST submit their CITI Human Subjects Training certificates.

If you are a student researcher, please make sure to attach the CITI certificate of your faculty advisor (PI).

***What do you need?***

* You only need to include a PDF document which you can download from the CITI site.
* DO NOT include a link or image of your completion report.

The CSUSB IRB requires one of the two (2) human subjects training modules noted below:

* **Group 1 -** Biomedical Research Investigators and Key Personnel: Those in the medical sciences, such as Biology, Chemistry and Nursing should complete this module.

OR:

* **Group 2 -** Social Behavioral Research Investigators and Key Personnel: Those in the social sciences, such as Psychology, Social Work, and Sociology should complete this module.

Access to the IRB Human Subjects Training site can be found in this webpage:

[https://www.csusb.edu/institutional-review-board/h...](https://www.csusb.edu/institutional-review-board/human-subjects-ethics-training)

**BELOW please attach CITI certificates in PDF files:**

<< ATTACH>>

# 3. DATA COLLECTION

\*required

Enter the proposed start date of your study. Please allow 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 (estimated) number of participants proposed for your study: \_\_\_\_\_\_

### **Demographic Information:**

Gender:

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 years of age 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 your research, please indicate "I am not seeking funding".

Select appropriate choice below:

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

Internal (Funding from CSUSB)

External (Funding from organizations/agencies outside the University)

# 5. REVIEW TYPE

Research is defined in the Code of Federal Regulations under [45 CFR 46.102(d)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102) as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Most research with children cannot be reviewed under Administrative (Exempt) review, and the application would require either Expedited or Full Board review. [See OHRP regulations.](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.401)

**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 [Non-Human Subjects Research](https://www.csusb.edu/institutional-review-board/irb-review/categories-review/non-human-subject-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)

\*\* check this only if your project is not considered human subjects research and you need the IRB to provide you with an NHSR determination letter.

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). Investigators who believe their project qualifies as NHSR SHOULD fill out this NHSR Guide as a worksheet to determine if their project falls in the IRB's non-human subject research category. If an investigator determines their project is considered NHSR and if they don't need a determination letter, they can start their project. In this case, there is no need for the researchers to submit the worksheet to the IRB either.

Important note: any investigator that inappropriately determines their study NHSR would be subject to the CSUSBs non-compliance reporting requirements to the Office of Human Research Protections (OHRP).

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 Cayuse Human Ethics (IRB) 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 (see Section 3 below for more details).

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

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

**PART A: RESEARCH < Non-Human Subjects Research Template, Cont'd>**

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 not-human subjects research requirements, you do not need to complete sections 6 - 12 on the left side of the application.

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

Does the proposed activity involve a systematic approach?

Yes\_\_\_

No\_\_\_

Is the intent of the proposed activity to develop or contribute to generalizable knowledge?

Yes\_\_\_

No\_\_\_

\*If Yes to both #1 and #2, the activity constitutes "research." Please continue to Part B to determine if this research involves human subjects.

\*If Yes to either #1 or #2, the activity may still constitute "research." Please continue to Part B to determine if this research involves human subjects.

\*If No to both #1 and #2, the activity may not be "research." However, you should continue to make a determination in the following sections.

**PART B: HUMAN SUBJECTS < Non-Human Subjects Research Template, Cont'd>**

Human subject – a living individual about whom an investigator (whether faculty, student, or staff) conducting research obtains: (1) information or biospecimens through intervention or interaction with the individual; or (2) identifiable private information or biospecimens.

Intervention includes both physical procedures by which information is gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable private information (or biospecimen) is private information/biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information/biospecimen.

Coded data means a living individual’s identifiable information such as name or social security number has been replaced by a code, such as a number, letter, or combination thereof and there is a key to link the code to the identifiable information of that individual. Coded data are considered identifiable private information (if the investigator possesses the key to identify a particular subject).

Secondary Data Analysis \*Publicly available datasets for secondary data analysis are not considered identifiable private information only when they fulfill both of the following conditions:

1. if the investigators do not hold the keys to identify particular subjects, and

2. if the investigators cannot readily pinpoint the identity of particular subjects through examining other demographic characteristics or variables in the data.

Does the activity involve obtaining pre-existing information or specimens about living individuals through intervention or interaction with the individuals?

Yes\_\_\_\_

No\_\_\_\_

Does the activity involve obtaining or the use of identifiable private information or specimens about living individuals? (See elaboration below)

Yes\_\_\_\_

No\_\_\_\_

When considering #2, please note that the following data arrangements are not considered identifiable private information/specimens and may qualify a NHSR determination. However, to obtain a letter of NHSR determination, the IRB may require a copy or an email exchange on these arrangements. See Section 3 below for detail if you need a letter.

1. The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances, until the individuals are deceased.

\*This may include publicly available data for secondary data analysis, such as the U.S. Census, General Social Survey (GSS), National Health Interview Survey (NHIS), American National Election Studies (ANES), etc. The investigators do not hold the keys to identify particular subjects and cannot otherwise pinpoint the identity of particular subjects by examining demographic characteristics or other variables.

1. The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased.

\*This may include publicly available data for secondary data analysis from organizations such as the Inter-university consortium for Political and Social Research (ICPSR).

1. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.
2. The investigator obtains publicly available information from internet sources. The internet site has obtained permission from users to release their information. Please review the internet site's privacy statement. (The internet site may prohibit use of their information or may require their written permission prior to use.)

\*If Yes to #1 and/or #2, the activity involves human subjects in Part B. You are required to submit a full protocol to the IRB if you also answered Yes to #1 and/or #2 in Part A.

### **SECTION 2: DETERMINATION OF “HUMAN SUBJECT” PER FDA REGULATIONS**

**< Non-Human Subjects Research Template, Cont'd>**

PART A: 21 CFR 50.3(G): Human subject – an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Does the activity involve individuals (healthy or patient) who will be a recipient of any test article (i.e., drug, biologic, or medical device)?

Yes\_\_\_\_

No\_\_\_\_

Does the research involve and individual on whose specimen\* a medical device will be used (21 CFR 812.3(p)) (i.e., In vitro diagnostic\*\* device?

Yes\_\_\_\_

No\_\_\_\_

\*If YES to #1 and/or #2 in section 2, the activity involves human subjects. You are required to submit a full protocol to the IRB if you also answered Yes to #1 and/or #2 in Part A.

Note: The FDA regulations (21 CFR Parts 50 and 56) apply to all clinical investigations regulated by FDA, as well as other clinical investigations that support applications for research or marketing permits. Therefore, all studies of investigational IVDs that will support applications to FDA are subject to 21 CFR Parts 50 and 56, even if they are not subject to most requirements of 21 CFR Part 812. For more information see the FDA Guidance on In Vitro Diagnostic Device Studies - F\*Specimen – including use of leftover specimens that are not individually identifiable (e.g., a remnant of a human specimen collected for routine clinical care or analysis that would otherwise have been discarded).

\*\*In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae.

**SECTION 3: REQUESTING IRB DETERMINATION < Non-Human Subjects Research Template, Cont'd>**

You do not need to submit this information to IRB if you have determined independently that your research is Non-Human Subjects Research according to the above guidelines. This application only applies to one the following conditions:

a. You need a letter from the CSUSB IRB indicating a Non-Human Subjects Research determination for your investigation. This letter may be presented for the purposes of grant applications, publications, thesis and dissertation completion; or

b. You are uncertain whether your investigation is Non-Human Subjects Research and would like the CSUSB IRB to provide you with a determination.

Please note, this is just a template and you need to submit all information below into the online submission application for the IRB to receive your NHSR application.

1. Check a category relevant to the proposed activity or investigation

Purpose/Aim is Social Behavioral

Purpose/Aim is Biomedical

2. Briefly describe the purposes of the proposed activity or investigation. Discuss if your activity or investigation involves systematic involves systematic approaches to anticipate generalizable knowledge

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3. Provide a brief Description of the procedures of your activity or investigation. Discuss also if your activity or investigation involves intervention or interaction with living individuals.

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4. Describe the subject population, sample, or the type of data/information/specimens involved in your activity or investigation.

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Please noted you do not have to fill out the rest of the IRB application if you have answered the questions above. **< End of Non-Human Subjects Research Template>**

## **Human Subjects Research**

Please 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, please 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.

The IRB has the final decision on the appropriate review category. We will inform you if you check the wrong one.

IMPORTANT: 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:**

Exempt Categories: Check the appropriate box(es) that apply to your study, if none of these categories apply to your research, please 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:**

\_\_\_ (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 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**

Expedited Review: Studies possessing no more than minimal risk. Expedited Review Applicability: Please check the appropriate box(es) that apply to your study, if none of these categories apply to your research, please 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.

(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.

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], 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). 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) 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.

**Expedited Category 9:**

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

### **\_\_\_ 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).

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## **B. Background Theory and/or Literature Review.**

Please be concise so reviewers can evaluate the merit of the study.

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## **C. Hypothesis or Research Questions.**

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## **D. Recruitment & Data Collection:**

1. Recruitment: Please describe how you plan to recruit or sample participants (who, where, when, how long, how, through what means, etc.). Recruitment materials can be attached under the text box.
2. Data Collection: Please describe how data related to human subjects will be collected (where, when, how long, how, through what means, etc.).

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### ATTACHMENTS AREA FOR RECRUITMENT MATERIALS

**APPROVALS:**

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

**RECRUITMENT MATERIALS**:

Please attach flyers, advertisements, e-mails, invitation scripts, etc. Most recruitment materials require these elements:

* 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)

**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 RECRUITMENT MATERIALS HERE>>**

## **E. Methodology and Data Analysis**

(and other data collection issues if they have not been mentioned in section D)

Briefly describe how you will organize and analyze data collected.

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## **F. Instructions, Instruments, Surveys, Questionnaires, Interview Questions, & Other Measurement Instruments. Please attach the files here:**

**<<ATTACH INSTRUMENTS 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?

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## **H. COVID-19 Related Questions (Optional)**

Please pay attention to announcements from the CDC and California Department of Public Health regarding increases in the spread of COVID-19 variants and sub-variants. 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

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# 7. CONFIDENTIALITY

Please discuss issues of confidentiality. Different stages of the research may involve different concerns over confidentiality. Please discuss these issues during the stages of recruitment, data collection, data storage, publication, and data sharing.

**RECRUITMENT**: Consider if potential participants will be known by others during the recruitment process. This is especially important if you are recruiting from stigmatized groups or vulnerable populations.

**DATA COLLECTION**: Is data collection occurring in areas of privacy? If not, please explain (e.g., in focus groups or ethnographical settings).

**DATA STORAGE:** Please 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.

We generally recommend CSUSB researchers to store digital data in **Google Drive or One Drive** under CSUSB accounts (with duo Security for Multi-Factor Authentication). If it is necessary for you to store data in personal computers or portable devices like laptops or USB drives, please explain and provide justifications and develop measures to protect those devices.

**DATA DISPOSAL:** If applicable, please indicate when the data will be destroyed after the data collection process has been completed. If not possible, state why.

**DATA ENCRYPTION**: If you are collecting sensitive data (e.g., those related to criminality, sexual/gender identities, citizenship statuses, stigmatized statuses, etc.), please consider data encryption and describe how you will encrypt data collected.

**RECORDINGS:** 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, digital deletion)?

**DATA SHARING/PUBLICATIONS**: Discuss if data (or findings) are to be shared with other collaborators. Discuss the treatment of people's identities in publications/presentations.

**DIGITAL DATA TRANSFER:** 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**. Anonymous data are data recorded so that the information can never be linked to the participant who supplied it, and the researchers do not know the identity of the participants either. Confidential data are data collected in a way that the participant could be identified by the researchers from the data. Researchers need to decide how to protect participants' identity and privacy throughout the research process.

\*\* If your research cannot guarantee the confidentiality of research participants, you will need to provide your reasons here and inform your research participants clearly in the consent process.

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# 8. RISKS, BENEFITS, INCENTIVES

## 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. Please also indicate any precautions or measures that will be taken to minimize risks. Risks and benefits **MUST BE** included in the protocol and in the informed consent document.

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## 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 with specific training or certifications, 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).

**Note: Any compensation granted to the participant is *NOT* a benefit of the study; it is an incentive (explain below).**

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## 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. Please take note of the following issues:

Compensation cannot be so great that it entices participants to engage in any activity to which they are averse, or to act against their better judgment. The following regulatory requirements and ethical principles must be considered when developing a compensation plan associated with any research protocol.

1. Researchers must avoid coercion and undue influence. The following definitions have been adapted from the federal Office for Human Resource Protections (OHRP) guidance on minimizing the possibility of coercion or undue influence:

* **Coercion**. Compensation is considered coercive if it entails an overt or implicit threat of harm/negative consequence which could compel involuntary participation and/or compliance. For example, telling a prospective subject she will lose access to needed services if she does not participate in the research is coercive and would not be permitted.
* **Undue influence**. Compensation that includes an excessive or inappropriate reward or other overture may constitute undue influence. For example, offering college students $100 or more each to complete a 20-minute survey on illegal drug and alcohol use could be viewed as unduly influential because the amount could entice students to disclose information that they would not otherwise willfully disclose to strangers.

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# 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 be written at the **5th or 6th-grade reading leve**l.

A template of an informed consent form is provided on the [IRB website](https://www.csusb.edu/institutional-review-board/irb-review/forms-and-templates) or here: [Informed Consent Example](https://www.csusb.edu/sites/csusb/files/EXAMPLEINFORMEDCONSENT12-12-13.doc). You do not have to follow the example format, but all informed consent (written, electronic, or oral) should include these **federally required elements**:

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

**Other Important Notes:**

* 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. Please attach the translated documents if appropriate.
* 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))
* 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 in anonymous surveys distributed in person or online, which also do not need to have consent with department letterhead). However, the CSUSB IRB still requires investigators to obtain consent for studies determined exempt.
* Informed consent should not include exculpatory language through which the participant is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence ([see here](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent-documents/index.html)).

**<<Attach Informed Consent forms/scripts here.>>**

## 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).

Below, please explain the kind of waiver of consent you are requesting. Researchers need to justify your request for a waiver of consent.

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## 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.

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# 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](https://www.csusb.edu/institutional-review-board/irb-review/forms-and-templates), or click this link: [Child Assent Form Example](https://www.csusb.edu/sites/csusb/files/child_assent_example.doc). The language level in the assent form should be appropriate for the age of the child.

Provide the child assent form as a written text in the text box OR attach the assent form/statement:

**<<Attach your Child Assent form here.>>**

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

# 11. DEBRIEFING

## Debriefing Statement:

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

## Emergency Contact Information and Other Resources:

The investigator may use this section to provide relevant contact information for the participants. This may also include additional information for counseling services or emergency hotline numbers for those experiencing distress after a research/study procedure. Please consider participants' emotional distress as a result of recalling past instances of psychological or physical trauma. You may also include an information sheet or emergency contact form (so titled) if needed.

Please refer to your faculty advisor if you are a student researcher.

Example of information to be included:

* Emergency Contact Information
* Suicide Prevention Help Lines
* Psychiatric/Psychological Services
* Counseling Services
* CSUSB Campus Resources
* Researchers Contact Information

**<<Attach your debriefing form/statement here.>>**

# 12. OTHER ATTACHMENT

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

**<< ATTACH HERE>>**

**\*\* END OF TEMPLATE\*\***