Submission Type: Initial Date: X-XX-XXXX

IRB #: IRB-FY20XX-XX

Title:

Creation Date: X-XX-XXXX

Status: Unsubmitted Principal Investigator:

#  A. Study Personnel

Welcome to the Initial Submission! Please complete each section. You can do this in one sitting or save your work and return to it after logging out.

When your submission is completed, you will be prompted to certify that the information you provided about your study is true and accurate.

Please note that additional information may be requested before your submission can be evaluated.

The initial submission must be approved before any research can begin.

\*required

Please identify the Principal Investigator (PI) for this project.

A1

Use the Find People button to identify the PI. If you are unable to find a person in the directory, please contact the IRB.

\*required

Please identify the primary contact for this project.

A2 Use the Find People button to identify the primary contact person. If you are unable to find a person in the directory, please contact the IRB at x2136 or irb@csudh.edu.

Name:

Organization:

Address:

Phone:

Email:

Please identify all other personnel associated with this study who will have access to the participants and/or data. This includes all co-investigators, research assistants, data

A3 analysts/statisticians, etc.

Use the Find People button to identify additional faculty or staff study personnel.

A3a

If you have student research assistants working on your project, you may attach a file listing each student's name, CSUDH email address, and major department or program.

A3b

If any non-CSUDH individuals are part of the study team, please provide their name, institution, and role on the study.

Attach CITI certificate or evidence of equivalent Human Subjects Research training for non-CSUDH study personnel in question K1.

Please note: all study personnel are required to have completed [CITI Program](https://about.citiprogram.org/en/homepage/) Human Subjects Research (HSR) training before the protocol will be reviewed.

\*required

What is the PI's role on the CSUDH campus?

Note: Due to a large submission volume, protocols will only be considered at this time if

A4 submitted by a CSUDH-affiliated PI.

Students may only be listed as a Co-Investigator; they are not eligible to serve as PI.

Faculty

✔ Staff Administrator

If this project is associated with funding by an external agency, use the Find Sponsor A5 button to identify the funding agency.

A5a If not found, name the source.

\*required

Where will study activities, including participant recruitment, data collection, and/or data analysis, be conducted? On the CSUDH campus, at off-campus locations, online or a combination? (Check all that apply.)

A6

For off-campus locations and organizations that will be involved in participant recruitment, data collection, and/or analysis, please briefly describe the activities taking place at each location.

✔ On the CSUDH campus

\*required

A6a Briefly describe the campus facilities or locations that will be used in the study.

✔ Off-campus

\*required

A6b Check all off-campus locations that apply.

✔ Elementary or secondary schools

\*required

A6b1 Please specify school names and locations.

✔ Other university campuses

\*required

A6b2

Please specify university names and locations.

Note: Other campuses may have differing IRB policies and may require external research to be reviewed by their research committee.

✔ Community sites or agencies

\*required

A6b3 Please specify community site names and locations.

✔ International locations

\*required

A6b4

Please specify international locations.

Note: If your research takes place in another country, travel must first be approved before your study begins, whether or not the university is paying for your travel. Refer to the [CSUDH](https://www.csudh.edu/rm/international-travel/) [International Travel Guidelines](https://www.csudh.edu/rm/international-travel/) for more information.

✔ Other location not listed above

\*required

A6b5 Please specify the other locations where your study will take place.

A6c

Attach a permission letter for each off-campus organization or location listed above where study activities will take place.

✔ Online

A6d

Please briefly describe the sites or platforms you will use to collect data.

Note: CSUDH supports the use of Dropbox for data storage and maintenance; Alchemer, Qualtrics, or Microsoft Forms for surveys; and QuestionPro for biomedical data. Refer to the Academic Technology for listed of IT approved software and platforms. [IT Approved List](https://at.csudh.edu/atsoftware.html)

#  B. Research Objectives and Background

\*required

Provide a one-paragraph summary of the study.

B1

Please describe the purpose/goals of the research and any study hypothesis or research question or outcomes of the study. You can tell us more about it in the next question.

\*required

In 500 words or less (one to two paragraphs), discuss relevant background information that justifies this proposed study. Cite references as appropriate to provide a rationale for the proposed research.

B2

Describe the scientific need or rationale for the study and the importance or significance of the knowledge to be gained. Please write as though you were explaining it to a colleague from a different discipline or profession.

#  C. Study Populations

\*required

Indicate any external adult subject populations you intend or expect to enroll in the

C1 research.

By external, we mean not affiliated with CSUDH.

✔ Healthy adult volunteers age 18-64

✔ Healthy adult volunteers age 65 or older

✔ N/A - none of the above

\*required

C2 Indicate any vulnerable populations you intend or expect to enroll in the research.

✔ Neonates (infants under 30 days old)

✔ Minors under 18 years of age (including CSUDH students under 18)

\*required

C2a Please describe the population of minors you plan to recruit, including specific ages.

\*required

For research involving minors, choose the proposed category of permissible

C2b

research with children.

This section is required if you indicated "Minors under 18 years of age" as a special subject population.

46.404 - Research not involving greater than minimal risk.

46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. NOTE: Financial or other incentives to participate in research do NOT constitute direct benefit.

46.406 - Research involving greater than minimal risk and no prospect of direct

benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

46.407 - Research not otherwise approvable that presents an opportunity to

✔ understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

✔ Cognitively impaired or mentally disabled individuals

✔ Physically impaired or disabled individuals

✔ Pregnant women and/or human fetuses

✔ Prisoners or detainees

✔ Individuals who may have impaired decisional capacity (including temporary impairment)

✔ N/A - None of the above

\*required

C3 Indicate any special subject populations you intend or expect to enroll in the research.

✔ CSUDH students

✔ CSUDH faculty, staff, or administrators

✔ LAUSD students, staff, or faculty

Committee for External Research ReviewNote: Approval from LAUSD's (CERR) [Committee for External Research Review](https://achieve.lausd.net/research)is also required before your study will be approved at CSUDH. Please upload your LAUSD CERR approval letter in section K1, "Additional Documents."

✔ Non-English speaking populations

✔ Undocumented immigrants

✔ Educationally or economically disadvantaged individuals

✔ Military personnel

✔ N/A - None of the above

#  D. Participants, Recruitment, and Compensation

\*required

D1 Please indicate the total number of participants to be recruited.

\*required

Will the data collection include multiple separate cohorts, sites, or phases?

D2

(e.g., enrolling both parents and children; recruiting students from several CSU campuses)

✔ Yes

\*required

D2a Please provide an explanation of participant accrual goals for all sites and subject populations.

No

\*required

Will the study involve the use of prospective or retrospective data? (Check all that apply)

D3

"Prospective" means that new data collection will begin after IRB approval. "Retrospective" means that the data analysis that begins upon IRB approval will use existing data.

✔ Prospective collection of data/specimens

✔ Use of existing or retrospective data/specimens

\*required

D4 Describe the inclusion criteria for enrollment.

\*required

Describe the exclusion criteria for enrollment.

D5

If there are any age, ethnic, language, gender, or other types of exclusion criteria, please provide justification.

\*required

Please select all of the methods you plan to use to recruit or include participants.

D6

Check all that apply

✔ CSUDH Psychology Student Pool

\*required

E6a Please describe.

✔ Flyers, brochures, or other printed advertisements

\*required

D6b Please describe.

✔ Mailers (US Post)

\*required

D6c Please describe.

✔ Newspaper or magazine advertisements

\*required

D6d Please describe.

✔ Radio or television announcements

\*required

D6e Please describe.

✔ Social media or other website posts or advertisements

\*required

D6f Please describe.

✔ Email, text messaging, or electronic mailing lists

\*required

D6g Please describe.

✔ Verbal/face-to-face personal solicitation

\*required

D6h Please describe.

✔ Snowball, chain-referral, or respondent-driven sampling

\*required

D6i Please describe.

✔ Amazon Mechanical Turk (M-Turk), Qualtrics panel, or other non-CSUDH pre-existing subject pools

\*required

D6j Please describe.

✔ Other recruitment strategy not listed above

\*required

D6k Please describe.

✔ No prospective recruitment (secondary analysis of existing data only)

\*required

D6l Briefly describe the source(s) of the existing data you will be using in this study.

Attach copies of all recruiting and advertising material that will be used. Include scripts and email/text message content. Recruitment material should identify the PI or study contact, and describe CSUDH and departmental affiliation. Please make sure to use

D7 your official CSUDH email.

Note: Flyers for print should maintain a 1.25" bottom margin in whitespace for IRB approval stamp.

\*required

Will subjects be compensated (financially or otherwise) for their participation?

D8

(e.g., gift card, research credit, course credit, other)

✔ Yes

\*required

Describe how much, if any, financial or other form of compensation will be provided to the participant. Describe the conditions that must be fulfilled to

D8a

receive full or partial compensation. Describe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.

No

#  E. Study Methods and Procedures

\*required

Describe in detail the design and methodology of the study. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation

E1 and endpoint definition. If applicable, include information on stratification or randomization plans. Include the frequency and duration of each activity, the location where each study activity will take place, and the total length of subject participation.

\*required

E2 Describe how the sample size was determined and how the data will be analyzed.

\*required

Please select all procedures that are applicable to your study. (Check all that apply.)

Note: The list of items below IS NOT an all-inclusive list of methods and procedures

E3 available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

All computer software used to collect or store study data must be approved by CSUDH IT. You can confirm which programs are currently approved by IT at the [Academic](https://at.csudh.edu/atsoftware.html) [Technologies website](https://at.csudh.edu/atsoftware.html).

✔ Audio recordings, video recordings, and/or photographic images

\*required

Please indicate:

how the audio, video, and/or image files will be captured and stored the time frame for transcribing or coding these files

the time frame for destroying these source files after

E3a

transcription/coding

Note: If you intend to publish, copyright, distribute and/or display any images or video resulting from this study, your participants will also need to complete

an [Audio/Video/Visual Image/Interview Release Form](https://www.csudh.edu/Assets/csudh-sites/ucm/docs/WORD-CSUDH-Visual-Audio-Video-Written-Release-Form-2018.pdf). This form should be

uploaded in section K1, "Additional Documents."

Note: If recording, include a separate line in the consent document seeking permission for recording and include information on why recording is necessary and what will be done with the recording during and after the study.

✔ Behavioral observations

✔ Behavioral interventions and/or experimentation

✔ Grades, quizzes/exams, or standardized tests

✔ Interviews and/or focus groups

✔ Ethnography, including online/virtual ethnography, and/or Photovoice

✔ Surveys, questionnaires, and/or psychometric testing

✔ Self-health monitoring (e.g., pedometers, food diaries, etc.)

✔ Noninvasive anthropometric measures (e.g., height, weight, waist circumference, etc.)

✔ Approved or investigational medical devices

\*required

E3b Please describe.

Note: For biomedical studies, the Human Subjects Bill of Rights ([English](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/bill-of-rights-english.pdf)/[Spanish](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/bill-of-rights-spanish.pdf)

) may be required for your study.

✔ Approved or investigational medications, supplements, or biologics

\*required

E3c Please describe.

Note: For biomedical studies, the Human Subjects Bill of Rights ([English](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/bill-of-rights-english.pdf)/[Spanish](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/bill-of-rights-spanish.pdf)) may be required for your study.

✔ Biospecimens/collection of human biological materials

\*required

E3d Please select all materials to be collected.

✔ Blood

✔ Urine/feces

✔ Saliva

✔ Nasal or cheek swab

✔ Skin

✔ Hair

✔ Fingernails

✔ Other sample or tissue specimen

\*required

E3d1 Please describe.

Note: For biomedical studies, the Human Subjects Bill of Rights ([English](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/bill-of-rights-english.pdf)/[Spanish](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/bill-of-rights-spanish.pdf)) may be required for your study.

✔ Creation of a data or tissue repository

✔ None of the above

\*required

Attach copies of all measures or instruments that will be used for this study. For analysis of existing data, attach a list of the variables you intend to include in your dataset.

E4

Note: Please attach the document as it will be seen by your participants – in other words, a printed version of your electronic survey. Do not provide an external link to it.

\*required

Describe where study records will be stored, including the types of devices used to store the information.

E5

Note: Identifiable data and coded/de-identified data cannot be stored in the same location. For electronic records, CSUDH supports Dropbox; requesting other data storage methods may lead to delays in study approval.

\*required

E6 Describe who will have access to study records, including how you have ensured that non-authorized personnel will not have access to the data.

#  F. Informed Consent

\*required

Please indicate the informed consent process(es) and/or documents to be used in this study. (Check all that apply)

Notes:

F1 - Please use the consent templates that are linked below based on your responses in

this section. You can download and modify these templates for your study.

* Consent forms need to maintain a 1.25" bottom margin for IRB approval stamp.
* If you are obtaining informed consent/assent or providing written or verbal information about the study in multiple languages, please upload all versions of these documents in the appropriate section.)

✔ Adult participants (age 18 or older)

\*required

F1a Check the type(s) of consent or waiver of consent planned for adult participants in this study.

✔ Written/signed consent (participants will sign an informed consent document)

\*required

F1a1

Attach a copy of the informed consent document(s) here. Please upload as a Microsoft Word (.doc, .docx) file.

Use the [Informed Consent Template](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/informed-consent-template.docx).

✔ An information sheet will be provided and/or verbal consent obtained (waiver of documented consent)

\*required

F1a2

Attach a copy of the information sheet(s) and/or verbal consent script(s) here. Please upload as a Microsoft Word (.doc, .docx) file.

Use the [Information Sheet Template](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/information-sheet-template.docx).

\*required

F1a3 Please provide a justification for not documenting consent from your adult participants.

Waiver of consent (participants will not be asked to sign a consent document or be

✔ given an information sheet)

\*required

F1a4 Please provide a justification for requesting a total waiver of consent from your adult participants.

✔ Child or adolescent participants

\*required

Check the type(s) of assent or waiver of assent planned for child or adolescent participants in this study.

F1b

Note: assent is generally expected to be documented for children age 7-17, unless the assent form would be the only identifiable object linking the child to the study.

✔ Written/signed assent (participants will sign an assent document)

\*required

F1b1

Attach a copy of the child or adolescent assent document(s) here. Please upload as a Microsoft Word (.doc, .docx) file.

Use the [Child or Adolescent Assent Form Template](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/child-adolescent-assent-form-template.docx).

✔ An information sheet will be provided and/or verbal assent obtained

\*required

F1b2

Attach a copy of the child or adolescent information sheet(s) and/or verbal assent script(s) here. Please upload as a Microsoft Word (.doc, .docx) file.

Use the [Child or Adolescent Information Sheet Template](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/child-adolescent-information-sheet-template.docx).

\*required

F1b3 Please provide a justification for not documenting assent from your child or adolescent participants.

Waiver of assent (participants will not be asked to sign an assent document or be

✔ given an information sheet)

\*required

F1b4

Please provide a justification for requesting a total waiver of assent from your child or adolescent participants.

Note: while waivers of documented assent can be granted in certain circumstances, it is very rare that a study providing no information about the research to its minor participants will be approved in studies of children age 7 or older.

✔ Parental permission

\*required

F1c Check the type(s) of consent or waiver of consent planned for parents/guardians of child or adolescent participants in this study.

✔ Written permission (parents or legal guardians will sign a consent document)

\*required

F1c1

Attach a copy of the parental permission document(s) here. Please upload as a Microsoft Word (.doc, .docx) file.

Use the [Parental Permission Form Template](https://www.csudh.edu/Assets/csudh-sites/gsr/docs/IRB/cayuse/parental-permission-form-template.docx).

Waiver of permission (parents or legal guardians will not be asked to sign a consent

✔ document or be given an information sheet)

\*required

F1c2 Please provide a justification for requesting a total waiver of permission from parents or legal guardians of your minor participants.

\*required

Clearly describe your procedures for obtaining informed consent, assent, and/or

F2 parental permission from all study participants. If procedures vary by cohort or over time, please explain.

#  G. Risk and Benefit Assessment

\*required

Describe the risks, discomforts, and potential harms associated with the research

G1 study. Include consideration of all physical, psychological, social, and other factors. (Check all that apply)

✔ Privacy - there is a small risk that people who are not connected with this study will learn a participant's identity or their personal information.

✔ Emotional (minor) - some questions may make the participant feel uneasy, embarrassed, or uncomfortable.

Emotional (major) - some questions discuss highly sensitive topics, including experiences of

✔ violence, victimization, abuse, and/or trauma. Participants with pre-existing emotional vulnerabilities may experience emotional distress as a result of study procedures or measures.

✔ Social - participants may disclose stigmatizing or sensitive information in settings where other people learning this information is a part of the study design (e.g., focus groups).

Economic/legal - participants are providing highly sensitive, personal information in this study. If people not connected with the study learn this information, participants could have problems

✔ getting a new job, keeping their current job, finding housing, or getting insurance (health, disability, or life insurance). In the most extreme situation, some participants could face deportation or be charged with a crime.

✔ Physical - study procedures may cause participants to experience physical discomfort or pain.

\*required

List the study procedures that are likely to lead to discomfort or pain.

G1a

Estimate the severity of the pain or discomfort to be experienced, and provide a justification for requiring physically painful study procedures.

✔ Biomedical - study procedures include drugs, medical devices, biologics, radiation, surgery, or other biomedical research procedures.

\*required

List all drugs, medical devices, equipment, procedures, or radioactive materials to be used in the study and provide a detailed description of each with justification for its use.

G1b

\*Note: The Subject Bill of Rights form is required by the State of California for studies involving drugs or radioactive materials. Contact the Research and Sponsored Programs office for appropriate forms.

Genetic - some people may find it upsetting to learn that they have certain mutations or errors in

✔ genes that could lead to future health problems for themselves or their children, or cause them to face discrimination based on genetic findings.

✔ Other - other likely risk not previously described.

\*required

G1c Please specify.

\*required

G2 Will the study involve any elements of deception?

✔ Yes

\*required

G2a Please provide a brief description and justification for the deception.

\*required

G2b Include a script or explanation of how participants will be fully debriefed.

No

\*required

G3 Choose the response that best describes the financial cost to participants, including travel and other costs associated with participation.

There are no costs related to participation.

All costs are covered by the sponsor or funder.

Research costs are paid by the sponsor or funding agency; routine health care costs are the responsibility of the participants and/or their healthcare plans.

All costs are the responsibility of the participants and/or their healthcare plans.

✔ Other

\*required

G3a Please specify.

\*required

If participants require care, medical services, or psychological services as a

G4 consequence of the research, who will provide this care? If applicable, describe who will pay for research-related injuries.

\*required

G5 Does your research include the potential for disclosure that a participant may engage in self-harm or attempt suicide?

✔ Yes

\*required

A Standard Operating Procedure (SOP) for suicide prevention is required for your study. Please attach your suicide prevention SOP here.

G5a

For more information about this requirement, see the UC Berkeley Suicidal Ideation in Protocols [guide](https://cphs.berkeley.edu/suicidal_ideation.pdf) and [decision tree](https://cphs.berkeley.edu/suicidal_ideation_decision.pdf).

No

\*required

Describe any potential for direct benefits to participants in the study.

G6

Note: Financial or other incentives for participation (gift cards, extra credit, etc.) do not count as benefits for this analysis.

✔ There are no direct benefits to research participants

✔ Participants may learn new knowledge or gain new skills

✔ Improvement in participants' physical or mental health

✔ Improvement in participants' survival or longevity

✔ Information gained from testing or monitoring procedures as part of the study

✔ Provision of materials or resources the participants would otherwise have to pay for

✔ Other direct benefit

\*required

G6a Please explain.

G7 Describe any potential for benefits to humanity as a result of your research. (Check all that apply)

✔ Contribution to the literature and broader knowledge base on your topic

✔ Improvement in a program, organization, or agency that serves the population under study

✔ Other

\*required

G7a Please explain.

\*required

G8 Risk/benefit analysis: Please indicate your agreement with one or more of the following statements. (Check all that apply)

✔ The potential benefits to the research participants justify exposure of the participants to the risks.

✔ The potential benefits to humanity justify exposure of the participants to the risks.

✔ Other

\*required

G8a Please explain.

#  H. Privacy and Confidentiality

\*required

Privacy is a participant's ability to control how other people see, touch, or

obtain information about them. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal

H1 behavior, or disclosing personal information such as gender or sexual identity, legal status, illegal drug use, or sexual behavior.

Please describe how you will protect the privacy of participants during screening, consenting, and conduct of the research.

\*required

Confidentiality is an extension of the concept of privacy, referring to the participant's understanding of, and agreement to, the ways identifiable information will be collected, stored, and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.

H2

How will your research data be labeled? For this question, "data" includes all information collected during the study, including but not limited to audio and video files, biological specimens, responses to surveys, questionnaires, or tests, and information entered into or stored in databases. (Check all that apply)

✔ Identifiable: Data will be directly labeled or stored with personal identifying information.

✔ Coded: Data will be labeled with a code that the research team can link to personal identifying information.

✔ Anonymous: Data will not be labeled with any personal identifying information, nor with a code that can be linked to personal identifying information.

✔ Other

\*required

H2a Please describe your other method of labeling data.

\*required

Do you intend to access, review, collect, use, or disclose protected health information (PHI) in your research? Check all personal identifiers that you intend to access or use

H3 below.

Check all that apply.

✔ Name

✔ Address (all geographic subdivisions smaller than state, including street address, city, county, and zip code)

✔ All elements except years of dates related to an individual, including birthdate, admission date, discharge date, date of death, and exact age if over 89.

✔ Telephone number

✔ Fax number

✔ Email address

✔ Social Security number

✔ Medical record number

✔ Health plan beneficiary number

✔ Account number (such as Student ID number)

✔ Certificate or license number

✔ Any vehicle identifier or serial number, including license plate number

✔ Any other device identifier or serial number

✔ Web address/URL

✔ Internet Protocol (IP) address

✔ Biometric identifiers such as finger or voice print, including audio recording

✔ Photographic image (note: photographic images are not limited to images of the face)

✔ Any other characteristic that could uniquely identify the individual

\*required

H3a Please specify.

✔ N/A - No member of the research team will have access to any personal identifiers at any time.

\*required

Is your use of protected health information (PHI) limited to "activities preparatory to research"?

That is, for all the personal identifiers you checked off above:

Are you only using them to identify and reach out to potential subjects?

H4 Can you ensure that personal identifiers will not be stored with your research data at any time?

Note: collecting personal identifiers after study participation, such as for incentive payments, does not count as "activities preparatory to research" even if those identifiers are collected and stored separately from your data.

✔ Yes - my use of personal identifiers is limited to activities preparatory to research

\*required

Please clearly explain how personal identifiers will be used in your study,

H4a

including how they will be collected and stored separately from research data.

No - I am keeping personal identifiers in my data and/or using them in analysis

N/A - No member of the research team will have access to any personal identifiers at any time

\*required

H5 Will any data, files, specimens, etc. be released to a third party, such as a study sponsor, federal agency, or another institution?

✔ Yes

\*required

H5a Will identifiable data, or a link between identifiers and coded data, be released to the third party?

✔ Yes

\*required

H5a1 Please explain.

No

\*required

H5b Please list any third parties who will be receiving study data.

No

\*required

What will happen to the research data at the conclusion of the study?

H6 (e.g., the data will be destroyed at the conclusion of the study, or the data will be maintained for 3 years after the conclusion of the study and then destroyed, etc... If study includes an online survey component please describe when you will close access to the survey.)

\*required

Do you have, or plan to obtain, an NIH-issued [Certificate of Confidentiality](https://grants.nih.gov/policy/humansubjects/coc.htm) for this study?

H7

Note: Most studies at CSUDH do not need a Certificate of Confidentiality. If you've never heard of this or are unsure whether you need one, you can select "No."

✔ Yes

\*required

Please attach the Certificate of Confidentiality.

H7a

No

#  I. Conflicts of Interest

This section covers pre-existing personal, professional, or social relationships that may create general and financial conflicts of interest (COI). These questions apply to each person who has responsibility for the design, conduct, and/or reporting of the research, as well as their spouses or domestic partners and any dependent children.

The PI is responsible for verifying this information with all members of the study team at study submission and on an annual basis thereafter. Any changes should be reported promptly to the IRB. Individuals are responsible for notifying the PI of any changes to their COI status.

\*required

I1 Check each applicable box below if any study personnel, or their spouses, domestic partners, or dependent children:

✔ Have a pre-existing relationship with the subjects (or potential subjects) of this research

For example, the research subjects are your students or former students.

✔ Have a pre-existing relationship with any external agencies or groups involved in this research

✔ Have been involved with the development of any materials or products affiliated with this research

✔ Have directly benefited or stand to benefit from the research or commercialization of its findings

Note: not including academic benefits such as course completion, publications, etc.

✔ Have anything about their involvement in the research that may appear to outsiders to be a conflict of interest

✔ N/A: Have no relevant pre-existing relationships to report

\*required

If you checked any potential general conflicts above, please use this box to explain the source of the real or apparent conflict of interest, including the role of that person (or

their spouse, partner, or child) in the research.

I2

If you only checked N/A, please verify by writing: "I confirm, on behalf of all study

personnel, that no person involved in the design, conduct, and/or reporting of this research, nor any spouse, domestic partner, or dependent child of study personnel, has any general conflicts of interest to report."

\*required

Check each applicable box below if any study personnel, or their spouses, domestic partners, or dependent children:

I3

Note: This section is restricted to financial interests that are related to this human subjects protocol. Financial interests that are unrelated to this protocol do not need to be disclosed.

✔ Have or plan to have an ownership, royalty, or other interest in any intellectual property associated with this research

✔ Have or plan to have consulting arrangements, responsibilities, receipt of honoraria, or income from any external entities associated with this research

✔ Have or plan to have a financial relationship, such as equity holdings, stock, or stock options as payment, with any external entities associated with this research

✔ Serve or plan to serve as a member of an advisory board or participate in any fiduciary or management role with any external entities associated with this research

✔ Receive or plan to receive any gifts or funds from any external entities associated with this research

✔ N/A: Have no financial conflicts of interest to report

\*required

If you checked any potential financial conflicts above, please use this box to explain the source of the real or apparent conflict of interest, including the role of that person (or their spouse, partner, or child) in the research.

I4

If you only checked N/A, please verify by writing: "I confirm, on behalf of all study

personnel, that no person involved in the design, conduct, and/or reporting of this research, nor any spouse, domestic partner, or dependent child of study personnel, has any financial conflicts of interest to report."

#  J. Researcher Qualifications

\*required

Summarize the research team's qualifications to conduct this project.

J1

Include prior research and training.

#  K. Additional Documentation

Attach any additional documentation not requested elsewhere, such as authorization to access restricted data from an agency outside of CSUDH, letters of support from

K1 external entities, permission to use copyrighted material, CITI training for outside study staff etc.

If there is any additional information you would like to provide that was not specifically K2 requested, such as a related pre-Cayuse study protocol number, clarification to earlier

questions, etc., please do so here.