Submission Type: Initial Date: 4-6-2026

IRB #: IRB-26-49
Title: change title here.
Creation Date: 3-9-2026
Status: Unsubmitted
Principal Investigator:

Core Info- Funding, Review Category

If you are unsure about a question or if you want to know what details the IRB is looking for in your answers, please click on the gray "?" at the right of each question for hints and advice.
[v18]

*required

In what general discipline(s) is your proposed research with human subjects?

Biological or clinical science (biomedical), e.g,. nutrition and kinesiology.

Social science, behavioral science, or education (SBER), e.g., consumer preference and psychology.

A combination of biomedical and SBER

Other

*required

What kind of funding or support do you have for this study with human subjects?

Federal such as NSF, NIH, DoD, DoE, DoEd, etc.

State agency such as CARB, California Dept. of Ed., etc.

CPP program such as McNair, Trio, Office of Research, etc.

Other type, such as private sources.

None

*required

Are you collaborating with another group such as a school, community association, government agency, etc.?

Yes

No

*required

Under which IRB review category would you consider that your study will fall?

The IRB will make the final determination

Exempt (includes the CPP designations of Studies of Assessment and Evaluation (SAE) and Policy on Educational Improvement Protocol (PEIP) - see the "?" for details)

Expedited (the review category, not the speed of review)

Full Board

Personnel- PIs, status, training, facilitator

*required

Identify your status as it applies to this IRB protocol.

For example, a staff member enrolled in a CPP master's degree program would choose "Graduate Student".
Responsibilities of a Faculty advisor - *Information sheet*

- Undergraduate Student
- Graduate Student
- Faculty
- Staff
- External Researcher
- Unaffiliated Investigator
- Other situations and explanations of anything in this section

*required

Principal or Primary Investigator (PI)

Human Subjects Protection Training - PI

Please provide your CITI ID number, completion date, and expiration date and attach a copy of the CITI transcript. For help, open the "?" at right.

*required

Who is the Primary Contact (e. g., study director, lab manager)?

Unless there is someone designated for this purpose within your research group, enter yourself with the **FIND PEOPLE button.**

Name: Elizabeth Mendoza
Organization: Office of Research Compliance
Address: , Pomona, CA 91768
Phone:
Email: emendoza7@cpp.edu

*required

Will you be using research assistants?

Research assistants are typically students helping with the study.

Yes

No; if this should change, you can amend/modify the protocol later to include them.

Section 1- Research Focus & Concepts

Research, for IRB purposes, is defined as a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.? http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

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*required

Describe the purpose of the study.

Why are you conducting this study? What are the goal(s), objective(s) and outcome(s)? What hypothesis or hypotheses are you testing or what are the research questions?

*required

State the relevance of the study.

State specifically the relationship of your proposed research to other, previous scientific and/or scholarly investigations in the field or to existing best practices. Include literature references.

Section 2- Methods

It is important that the procedures to be applied-some might call these treatments - to the human subjects are thoroughly explained and outlined. Those who will review and approve your study must fully understand what will take place during its conduct. Once approved, it is necessary that the procedures be carried out in the way they are officially described in this protocol.

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*required

Summarize the overall design of your proposed study.

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*required

Will you be testing a food product on participants or providing a nutritional supplement to participants as part of the study?

Yes

No

*required

Provide a step-by step outline of the activities included in this study.

What events will occur and in what order? How will the information about the study be presented to the participants?

Section 3- Subjects & Recruitment

The terms subjects and participants are often interchangeable. A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information. (Dept. of Health and Human Services, 45CFR46)

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*required

Describe the characteristics of the subject group(s) that will be used in the study.

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*required

What is the study's expected sample size?

How many subjects (or participants) will be involved in the research project? How did you determine your sample size?

*required

Will subjects be compensated, meaning something they get or receive from participating? If the proposed research is funded through a grant or contract, investigators must abide by CPP foundation policy AP 253

Yes

No

*required

What are the benefits, if any, to the subjects from their participation in the study?

The terms benefit and compensation have their own meanings in the IRB setting. For example, a cancer patient is paid $100 as compensation for a tissue biopsy and may receive benefit learning about a gene predictive of treatment. Please answer these questions appropriately.

*required

How will you recruit your potential subjects to participate in the study? From where will you recruit them?

Defining and describing the recruitment helps to standardize what is said to the potential subject. It does not need to be as detailed as the informed consent form (ICF), but must be consistent with the same information.

***For research recruitment on the Cal Poly Pomona campus reference and comply with all policies outlined in the University's Policies website regarding *Posting and Chalking*.

Attach any recruitment materials you will be using with your application.

Provide below the text of the script, e-mail, posted flyer, etc. Include the statement as follows: The Cal Poly Pomona Institutional Review Board has reviewed and approved for conduct this research involving human subjects under protocol IRB YY - ### (meaning year and sequence number, e. g., IRB 24-123)

Attach any authorizations for recruiting on electronic or at physical sites.

Authorizations and permissions to conduct studies are not equivalent to informed consent forms. To recruit from/on online (Internet sources, blogs, chat rooms), provide documentation allowing for the research from the moderator or from the site's terms and conditions.

*required

Are you collaborating with another group for recruiting purposes, such as a school, community association, government agency, etc.?

Please explain and attach any approvals/permissions

Yes

No

*required

Will translation of materials be necessary to other languages or to a different reading and comprehension level for recruiting purposes?

Consider that children often need simplified language. Studies show that the average adult reads at a 5^{th} to 8^{th} grade level.

Yes

No

*required

Describe your procedures for the recruitment of a representative sample of the population. Is your recruitment based upon race, ethnicity, gender, health status, or other characteristics?

If this is not the case, discuss the reasons for not having such a balanced sample (such as, the research is focused on a certain subject group or it's a case study).

Section 4- Data Collection

Collection methodologies include, but are not limited to: surveys, interviews, focus groups, observational research in public schools, physiological sensors, weight scales, and the extracting information from existing data sets.

Data include: the information (responses) on survey sheets and questionnaires, biological samples, audio and video tapes, interview questions.

Personal and private data deemed by the IRB to be a risk to subjects if revealed include: gender, income, number of children, age, religion, ethnicity, e-mail addresses, and more. Even when labeled as "demographic" data, it is still personal and private and could potentially identify an individual. The term is PII for personally identifiable information. Any information that can be used to distinguish one person from another and could then be used for de-anonymizing anonymous data can be considered **PII**. This is not to say that PII data should not be collected, but mechanisms must be described in this protocol to protect the interests of the subjects should they be (somehow) identified.

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*required

What type of data will you collect?

For example, the variables/responses to questions from surveys and interviews, the information extracted from transcripts after making audio and video recordings, data collected when reviewing medical histories, taking blood samples, measuring treadmill running times, asking for income, weighing the amount of food eaten, etc.

Will your research utilize any copyrighted materials, instruments, measurements, scales, etc. that were created by someone other than you?

Questionnaires, surveys, measurements, etc.

Yes

No

What methods will you use to collect data from participants?

Select all that apply.

Paper survey/questionnaires

Electronic survey/questionnaires

Interview

Audio/visual recording

Bio-specimens (blood draws, urine, saliva, etc.)

Focus Group

Exercise protocol

Archival/Secondary Data

Observation

Other

*required

Will your research take place in another country?

Yes

No

*required

Where will the research be conducted?

For example, a laboratory, a classroom, a hospital, field work, and other places.

Attach any authorizations obtained, allowing for conducting research at a location. For example, the superintendent of a school district, the owner of a business, the medical director of a clinic, and others.

*required

Will you be using any third (3rd) party online websites to collect data?

e.g. facebook, twitter, etc.

Yes

No

*required

Will you be gathering information from subject medical records?

Yes

No

*required

What is the estimated start date of the study?

Comments

*required

What is the estimated end date for data collection for this study?

Comments

Section 5- Vulnerable Subjects

When a subject has limitations, is coerced or manipulated, there is a loss of capability to volunteer, and the subject may be vulnerable. According to regulations, vulnerable subjects include prisoners, pregnant women, minors and fetuses. The IRB considers other kinds of vulnerability, for example, the possibility that bosses can coerce at the workplace and teachers can manipulate in the classroom. Research conducted with regulated vulnerable subjects requires demonstration of your training and experience with that specific population.

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*required

Will the research involve any of the following populations?

- Children, Minors, or Wards
- Pregnant Women
- Fetuses
- Prisoners
- None

*required

Will the research involve other vulnerable populations?

- Yes
- No

Section 6- Data Security

Per California law, CC 1798.24, the researcher must provide a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.

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*required

Is the study:

Anonymous

Justify

Confidential

Justify

None/Neither

*required

Will personally identifiable information (PII) be collected/used?

Yes

No

*required

Who will have access to the data?

Will any data collected from the study be made available as open access*? For example, some funders and journals request that data be housed (kept, stored) at an approved site (e.g., clinicaltrials.gov* ***or*** *understanding data sharing policies), accessible to the public.*

*required

How will the raw data be kept protected and secure?

How will it be coded or identified?

*required

What will become of the data at the end of the study?

*required

How will the data, results, and conclusions be utilized?

*Do you plan to use any data in a presentation, publication, or something else? Will any data be used *only* internally, for example within an institutional department?*

Section 7- Potential Risks & Their Assessment

Definition of risk: A potential harm, discomfort, or inconvenience associated with your research that a reasonable volunteer would be likely to consider significant in deciding whether or not to participate. Risks include legal, social, emotional, or psychological issues, physical or biological hazards, revealing an identity, damage to reputation, exposure of behavior or medical character, illness, injury, side effects of applied or consumed products, revealing or a loss of private information, etc. Risk comes at various orders of magnitude, ranging from mere inconvenience to perceptible bodily pain.

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*required

What are the risks? Describe any potential harm, discomfort, or inconvenience, however minimal, as you would explain them to the subjects.

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*required

Describe your procedures for protecting against or minimizing the potential risks stated above.

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*required

Explain why these risks should be determined as reasonable in relation to the anticipated benefits, if any, while conducting research with the subjects.

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*required

Will you utilize any of the following for the study's potential risks?

Check all that apply

- [ ] Debriefing Statement
- [ ] Counseling and Psychological Services (Ex. SHCS at CPP)
- [ ] Adverse event protocol (medical emergency services contact)
- [ ] None

Section 8- Affiliations

These questions ask about how you are related to the institution and subjects where the research project is to be conducted. As examples: you are a teacher using your students in a classroom setting as your subjects, or you work for the company where a marketing survey is to be conducted, or you have a financial interest in a product being tested. Each of these examples presents an element of risk. IRB reviewers will evaluate whether these risks are reasonable and whether they are sufficiently controlled, minimized, or eliminated by your procedures.

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*required

Do you have any kind of pre-existing relationships with the subjects (participants) or institutions involved in conducting this study?

Working at the place where the study is to be conducted may be seen as coercive to others. Consider the possibility that collection of data from either the participant or institution may be seen as a favor when asked to volunteer information. The IRB is interested in reading a statement from the PI(s) of the potential and it may be of no concern at all. See the "?" for more.

Yes

No

*required

As an investigator involved with the project, do you or any of your family members (e.g. spouse, child) have a financial or other self interest in this study?

Yes

No

*required

Though there may not be one, could there be the perception of a conflict of interest for either you, as the investigator, or for the subjects in this study?

Yes

No

Section 9- Informed Consent & Assent Form(s) (ICFs)

The informed consent form (ICF) is the means by which you as the PI convey not only the research, but also the principles of human subjects protections to your subjects: respect, beneficence, and justice*. There are examples on the*IRB website*. Towards the top of this web page is the Word protocol document which contains the elements for the ICFs and the required header in English and Spanish: "blank IRB protocol application for training, classroom exercise, and development."*

To test your ICFs for appropriate reading levels, submit your ICF to this software: www.hemingwayapp.com

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*required

Select the type of ICF you will utilize

Note that you should add the current IRB protocol number obtained when you created this protocol in Cayuse to your ICF(s) before you upload it to this site. Be sure to check the **list of required ICF elements** (available in the Word protocol document at the IRB website) and that the domain *csupomona* has been changed to *cpp* in email addresses and websites.

Informed Consent, paper version. This is the most typical means to explain a study and convey the ICF elements to potential subjects/participants.

Informed Consent, electronic version (sometimes called implied consent because the subject doesn't sign but instead **clicks** yes/I agree or no/I don't agree). This type of consent doesn't always work and may not be applicable in certain risky and potentially harmful studies.

Waiver of Informed Consent, when obtaining consent is not practicable in order to conduct the research; see the federal regulations

*required

Will there be recruitment of subjects who cannot themselves provide informed consent?

Yes

No

*required

How will you obtain and document informed consent?

See the "?" for more.

*required

Which study personnel will be involved in obtaining consent?

Know that makes such personnel ***engaged*** with the potential study subjects/participants.

*required

Describe how you will maintain and secure the consent forms received from the subjects?

Consent forms can be electronic or paper.

Section 10- Study PI(s) Declaration

THE CAL POLY POMONA IRB DECLARATION BY ALL INVESTIGATORS:

- This proposal is guided by the ethical principles regarding research involving human subjects as set forth in the Belmont Report.
- I/We agree to abide by the policies and procedures of the IRB at CPP, including obtaining appropriate training in human subject research for myself and those involved in its conduct.
- I/We will not initiate any research associated with this proposal on or off campus until authorized by the IRB.
- I/We will report to the IRB about any adverse events or unanticipated problems (unexpected, possible greater risk, etc.) that occur.
- I/We will inform the IRB of a need to modify the study design requiring an amendment.
- I/We understand that approval, when granted, is valid for up to one year and will submit a renewal for its continuation if needed.

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*required

By entering your name below, you as the PI are agreeing to adhere to the "CAL POLY POMONA IRB DECLARATION" above and are acknowledging responsibility for any co-PIs and research assistants listed in the protocol and their adherence to the "CAL POLY POMONA IRB DECLARATION"

Signature of Principal Investigator (please enter your name below):