Text Box

IRB #: (XX-XXX)

Title: Creation Date:

Status: Unsubmitted

Principal Investigator:

**A) 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.*

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

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

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

* Yes
* No

Under which IRB review category would you consider that your study will fall? Please explain your reasoning.

*\*The IRB will make the final determination*

* Exempt
* Expedited (the review category, not the speed of review)
* Full Board

Explain your reasoning

Shape

**B) Personnel- PIs, status, training, facilitator**

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".* |

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

Principal or Primary Investigator (PI)

Name:

Organization:

Address:

Phone:

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.

CITI ID:

Completion Date:

Expiration Date:

*\*\*\*\*Citi Completion Report PDF must be attached*

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. This will autofill with the person’s contact information*

Will you be working with persons outside of CPP? In other words do you have an external or unaffiliated co-PI?

* Yes
* No

If any, select the co-PI(s) for this studyShape

A co-PI applies when there is a collaborative research project being proposed in this protocol.

Human Subjects Protection Training

Please provide the CITI ID number, completion date, and expiration date for each co-PI and attach a copy of the CITI transcript.

CITI ID:

Completion Date:

Expiration Date:

*\*\*\*\*Citi Completion Report PDF must be attached*

Will you be using research assistants?

*\*Research assistants are typically students helping with the study.*

* Yes
* No

**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*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html) |

Describe the purpose of the study.

EXAMPLE:

Specific goal(s), Objective(s), outcome(s) 1:

* Independent Variables:
* Dependent Variables:
* Specific Hypothesis 1:

Specific goal(s), Objective(s), outcome(s) 2: (if applicable)

* Independent Variables:
* Dependent Variables:
* Specific Hypothesis 1:

State the relevance of the study.

Shape 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.

*\*Work cited must be included in this section.*

**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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Summarize the overall design of your proposed study.

Shape*\*Experimental Design (do not include timeline here)*

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

* Yes
* No

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?

*EXAMPLE:*

*Late April-IRB approval*

*Early May-send out survey through email*

*Mid-May-collect results, analysis of data, prepare descriptive statistics*

*Late May-use results to inform finalization of extended course outcomes.*

**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)*

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

Section 3- Subjects & Recruit

*EXAMPLE: “We are studying Sociology students at Cal Poly Pomona who are 18 years old or older.”*

What is the study's expected sample size?

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

*EXAMPLE: “Around 300-400 students across the Sociology courses should be taking the assessment. Sample size was determined by...”*

Will subjects be compensated, meaning something they get or receive from participating?

* Yes

*\*\*\*$150 compensation upon completion*

* No

*\*\*\*There will be no monetary compensation for the participants.*

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

*EXAMPLE:*

*“The benefits of participating in this study are as follows:*

*1. Receiving assessments for social skills.*

*2. Receiving 2 weeks of supervised behavior therapy.”*

*OR*

*“Though there will be no monetary compensation for the participants, they will be informed that their participation will help inform scholars, educational experts, and other students about the factors that greatly influence social skills.”*

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.*

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 17-123)*

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.*

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

Shape

*Please explain and attach any approvals/permissions*

* Yes
* No

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?

Shape *\*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*

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

Will your research take place in another country?

* Yes
* No

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.*

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

*\*e.g., Facebook, twitter, etc...*

* Yes
* No

Will you be gathering information from subject medical records?

* Yes
* No

What is the estimated start date of the study?

/ /

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

/ /

**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.*

Will the research involve any of the following populations?

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

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.*

Is the study:

* Anonymous (Justify)

*\*A* ***strictly anonymous*** *study design is one in which it is impossible to trace data or information back to the research subject from whom it was obtained. In other words, the data* ***cannot*** *be identified to any* *particular research participant, not even by the researcher.*

* Confidential (Justify)

***\*Confidential*** *research participation means that the data from the research subject(s)* ***can*** *potentially be identified or linked to a particular individual. Thus,* ***any*** *data collected face-to-face (consumer survey, focus groups, standing in front of a classroom, etc.) is automatically considered in the category of being confidential as opposed to anonymous.*

***Justify Reasoning***

* None/Neither

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

* Yes
* No

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), accessible to the public.

*\*\*\*Please name PI, Co-PIs and research assistants that will have access to the data.*

How will the raw data be kept protected and secure?

*How will it be coded or identified?*

*\*EXAMPLE:*   
  
 *“To keep the data protected and secured, the following steps will be followed:*

*(1) The PI will delete the survey from Qualtrics to not leave record of the responses.*

*(2) The data file will be stored in the PI personal computer that he only has access to. Also, the PI's*  *personal computer is password protected.*

*(3) The data file will be password protected and only the PI will have access to the file.”*

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

*\*EXAMPLE:*

*“Data will be kept indefinitely for possible future use but will be stored with the personal identifiable information omitted.”*

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?

*\*EXAMPLE:*   
 *“The data will be used in aggregated form to present at conferences and/or to write manuscripts for publication consideration to sociological journals.”*

**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.*

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

*\*It can be said that everything has a risk. Think carefully about what may potentially happen during your research. This information summarized must be included in the consent form.*

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

*\*Informing subjects that they can withdraw from the study is one way*

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

*\*Include in your response the importance of the expected gain in generalizable knowledge, when evaluated against the risks.*

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

* 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.*

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

If so, why?

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

If yes, how so?

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

If so, why?

**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 theIRB 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:* [*http://www.readabilityformulas.com/flesch-grade-le...*](http://www.readabilityformulas.com/flesch-grade-le)

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

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

* Yes
* No

How will you obtain and document informed consent?

*\*Could it be in person, electronically, etc.*

Which study personnel will be involved in obtaining consent?

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

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.

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”

Shape

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