Throughout this template, guidance information is provided in underlined and dark red text. You may delete the red text if desired. It is also expected that all researchers review the complete IRB guidelines available here: <https://research.calpoly.edu/HS-guidelines>

Not all sections below will be applicable to all studies. Either delete sections requesting information that is non-applicable or enter N/A in those sections. You may also re-arrange sections. This document is intended to provide broad support to those looking for assistance in writing a complete protocol, but is not a required template.

Anonymous vs. Confidential: Throughout your protocol, consent form, and other documents, pay particular attention to the user of these words. Participants can only be anonymous if even the researchers do not know their identities.

**Descriptive Project Title**

Use a descriptive title, “Jill’s Senior Project” is not descriptive. The title should contain basic descriptive information about the project. “A Senior Project Investigating the Impact of IRB Protocol templates,” is sufficient.

**Project Personnel**

Include all students, faculty advisors, faculty, and external collaborators who will be working with human subjects or Human Subjects data. Please note all personnel should also be listed on the IRB Manager Forms. All Cal Poly personnel have an account that they must activate by logging into IRBManager once using their Cal Poly Single Sign On ID and password. Please include names, role on the project, and institutional affiliation. Provide relevant qualifications of the investigator(s). These could include medical training in CPR when conducting physical tests, experience with vulnerable study populations, experience with the study methods, etc.

**Statement of Purpose and any Hypotheses**

In most cases, one or two paragraphs are likely to be sufficient. This statement should summarize information on the study purpose/objective and any hypotheses.

**Description of Risks and Benefits**

Describe the possible benefits to the field and any potential benefits for the research subjects. Address any potential risks to participants. Very few projects involve no risks to subjects. At minimum, the consider the following risks that may apply to your project:

(a) physical harm (e.g., pain, discomfort, injury, side-effects of drugs, dizziness),

(b) psychological harm (e.g., stress, guilt, depression, loss of self-esteem, confusion, embarrassment),

(c) social harm (e.g., the possible stigmatizing effects of diagnostic labels such as "delinquent" or "schizophrenic" or other impact to reputation or status such as disclosing someone’s sexual preferences or other behaviors that might be viewed unfavorably by others),

(d) economic harm or risk to employability or academic achievement (e.g., threats to employment if a subject's involvement in research on HIV carriers or alcohol abusers were revealed), and

(e) social, economic, and/or psychological harm could result from having subjects reveal illegal activities, such as underage drinking, substance use, etc.

**Subjects and Subject Characteristics**

Provide information about the persons who will be your research subjects. Provide information on the source (e.g., introductory psychology classes at Cal Poly, random sampling of public, or targeted population in the community); selection and exclusion criteria (if applicable); approximate number of subjects; whether prospective subjects are members of a vulnerable group or not; expected age range; and other descriptors that might be relevant (e.g., gender, ethnicity).

Please note, while certain vulnerable populations are described in the federal regulations, there may be other populations which might experience coercion to participate in a study (e.g., students in a researcher’s class, persons under medical quarantine).

Any research that collects data from those under 18 generally requires both parental consent and child assent. You may wish to exclude those under 18 unless your research specifically intends to answer research questions about children.

**Study Location**

Provide information on the location of the study. Also, describe any special considerations associated with recruitment or data collection at the location, such as, identifying potential subjects, location appropriate for obtaining informed consent, privacy/confidentiality concerns, etc. If a study involves an in-person component, please address safety protections related to COVID-19.

If the study contains a survey, the survey platform should be identified, and information should be included about the expected states and countries from which participants may complete the survey. There are many varying international regulations regarding online data collection, retention, destruction, and security.

If interviews or other interactions will take place via Zoom or phone, this section should so state.

Projects occurring on a K-12 educational site, or as part of a formal K-12 educational practice, require a letter from the appropriate administrator at the K-12 partner be uploaded to IRBManager as an attachment.

**Methods**

**Recruitment Process and Materials**

Please describe how subjects will be recruited to the study. Any recruitment materials such as, recruitment scripts, emails, text/images to be used in social media posts, flyers, etc., must be provided to the IRB, either within this section or as additional attachments in IRBManager. If you are using a commercial recruitment system (i.e., Mechanical Turk, Qualtrics panel), please so state and indicate what information is provided by that system to potential subjects (study title, incentive, etc.) and provide text if not provided elsewhere, such as a summary.

**Deception**

Describe any deception of subjects in the study. Deception may be approved when necessary to meet the research goals and the project poses very minimal risks. An example of deception would be telling participants that the study is about completing a short quiz, when the intention is to study the impact of interruptions on the subject’s ability to take the quiz. In rare cases, studies may also utilize prospective consent to deception, where subjects consent to being deceived as part of the consent process without knowing the specifics of the deception. Researchers interested in prospective deception or deception in studies with greater than minimal risk should contact the IRB to discuss.

**Intervention Procedures**

Describe any interventions that may occur as part of the project in this section. Interventions that occur within a survey or interview (i.e., watching a video, viewing and image), should be described in the respective data collection section/s. Examples of interventions include; having a participant run on a treadmill, hit a ball, engage in a specific educational practice (e.g., post-test journaling), attend a seminar or workshop, engage in daily meditation, change their diet, undergo an exercise regimen, testing a device, and many others. This section should describe the intervention itself, how it will be undertaken, possible risks, methods undertaken to avoid the risks, and other similar information.

**Data Collection**

Provide a general description of what data will be collected, and how it will be collected. There are additional sections below in which to provide more detailed responses. Projects may involve multiple types of data collection. In some cases, additional data collection methods may be added via the modification process, so do not include any data collection mechanism for which you can not provide all requested information. All requested information must be reviewed or approved by the IRB prior to starting that portion of the study.

NOTE about Demographic data: There is some debate about the value of collecting demographic data versus the risk. Please only collect the data you need to meet the research objectives. In cases where demographic data may allow for re-identification of participants, please consider grouping demographic options. For example, if you are collecting data from 20 people, of which 2 are Black and 1 is Latino, with the other 17 participants being White, it may be more appropriate to collect information only between “White” and “Person of Color” to reduce the chances of re-identification. Carefully consider the purpose of collecting data about biological sex and gender. If data about biological sex is required, please provide a justification for doing so within this document, recognizing that biological sex is not always a binary determination between female and male. If you are collecting information about gender, at minimum, three options must be available: female, male, and non-binary.

**Food/Beverage Sensory Testing**

Clearly identify the components of the food/beverages to be tested. Indicate if wholesome foods without additives are consumed, or if products include a food ingredient, agricultural chemical, or environmental contaminant at or below the level and for a use found to be safe by the Food and Drug Administration, the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture. Sensory tests not meeting those requirements may be approved, but need to be reviewed by the Full IRB, adding about a month to the review timeline.

**Surveys**

This section should include information about surveys, including surveys provided to collect demographic or other data prior to interviews or other data collection procedures. All survey questions must be provided to and approved by the IRB to receive approval of the project. For surveys that reference images, videos, or other media, the other media must also be provided to the IRB for review. All survey questions should be optional, except for any questions used to determine subject eligibility. When contact information is needed for follow-up or for other purposes, describe how that data will be collected, why it is needed, and why it must be associated with survey responses. If contact data does not need to be associated with survey responses, such as contact information collected for raffle purposes, the contact information should be collected in a secondary survey to ensure research survey responses remain anonymous.

**Interviews**

Describe how interviews will be conducted. Will they be in person, via phone, Zoom, etc.? Describe how/if interviews will be transcribed or if the research team will take notes during the interview. If notes are taken, indicate if they will be taken as paper notes, typing into an electronic device, etc. Clearly indicate if recordings will be made, and if such recording can be optional for subjects who do not wish to be recorded. Describe any transcription method applied to recordings, such as otter.ai, transcription by research team members, or transcription by an external service. Identify any external transcription service by name.

Provide all interview questions. Some interviews might be designed to include questions that are asked in response to previous answers. In that case, draft versions of the questions are acceptable, but if there are any substantive changes to the questions, they must be reported to the IRB as a protocol modification so that assessment of risk can be evaluated. Also, provide opening and closing scripts. The opening script should remind participants that they can end the interview at any time or skip any questions. It should also remind them of the purpose of the project and that the interview is being recorded. The closing script should thank subjects for their time and provide any other follow up information needed.

**Physiological Data Collection**

Describe what physiological data will be collected. If not addressed in a previous section, describe how the data will be collected. Physiological data may be more identifiable than other types of data, and this section should describe risks of re-identification of subjects based on the data collected, along with security measures put in place to reduce the probability of re-identification of subjects.

**Other Data Collection not Addressed Above**

Data collected that is not addressed in the categories above should be described here. Provide the same level of detail requested in other sections.

**Data Storage, Sharing, and Destruction**

Describe how data will be stored and the security measures that will be applied to reduce the possibility of accidental disclosure. Describe when/if data will be destroyed. If data will be destroyed, a month and year for the planned destruction should be included. If multiple types of data will be collected, such as interview recordings and survey responses, please indicate the data handling and destruction plan for each type of data. Indicate if data will be shared with other researchers or re-used for other research projects.

Please note, some journals may expect data to be shared as part of the publication process, such sharing should wherever possible be described within the protocol and indicated on the consent form.

**Data Monitoring and Participant Safety**

When appropriate, plans are included for adequately monitoring the data to ensure the safety of the subjects. Researchers are required to monitor their procedures carefully throughout the data collection process to reevaluate the risks to human subjects. If the risks are determined to be greater than initially predicted (e.g., an exercise protocol results in dangerous increases in heart rate), the IRB Chair or the Director of Research Compliance should immediately be notified and prompt, appropriate steps should be taken to reduce the risks, obtain additional informed consent, and/or discontinue the procedures.

**Incentives**

Describe any incentives provided to research subjects. Incentives might include gifts, extra credit, gift cards, or other payments. Incentives must not be so high in value to coerce subjects into participating. If extra credit is provided for research participation, students must have access to similar extra credit opportunities that do not require research participation and require similar amounts of effort.

There are special California regulations that apply to incentives provided via drawings or raffles. Drawings and raffles must be open to all, even those who do not elect to participate in the research activity or who do not fully complete the activity. The consent form and this protocol must both identify the odds of winning (must be equal to or greater than 1 in 1,000), the alternative method for entry into the drawing/raffle other than participation in the research, and the date on which winners will be notified.

**Process for Obtaining Informed Consent**

Describe the process and mechanisms for obtaining consent. Consent form templates are available here: <https://research.calpoly.edu/HS-forms-and-links>

In general, consent must be obtained from all research subjects, as well as their parents if subjects are under the age of 18. Cal Poly may waive signed consent for minimal risk surveys. In those cases, the consent form should be provided as the first question within the survey.

Signed consent forms may be collected with ink signatures or via an electronic signature mechanism. Any electronic signature mechanism should be specified in this section.

In some cases, Cal Poly may fully waive the consent requirement if the process of collecting consent is either not feasible due to the study population or if collecting consent and maintaining those records of participant identity are likely to cause greater risk to participants than not collecting consent forms.

For interviews, behavioral interventions, medical studies, and other projects with a scheduled or in-person component, consent forms must be provided to subjects prior to scheduling the interview or intervention so that they can review the consent without the potential for coercion.

Informed consent is considered a process, not a singular event. Any changes that affect the consent documentation must continue to be communicated to the subject for the duration of the subject’s enrollment in the project.

Researchers also may not ever require participants to waive the subject’s legal rights or to release the investigator, research sponsor, or the institution from liability for negligence.

If the project involves analysis of a pre-existing data set, please either describe how consent was originally obtained, or if consent was not obtained because the data was not collected as part of a Human Subjects Research activity. If consent was obtained, please include the original consent form as an attachment in IRBManager, if consent form language is available.

**Debriefing Statement for Projects Involving Deception and Incomplete Disclosure**

Provide the text of the debriefing statement that will be provided to subjects. This statement should include a description of the deception involved, an explanation about the true purpose of the research, inform the subjects of their right to withdraw their data from the study, and provide contact information for a referral in case the subject is upset or feels uncomfortable.