ELEMENTS OF THE PROTOCOL APPLICATION	SOP 4.02.05

1. Purpose & Policy

The purpose of this SOP is to outline the necessary elements that must be included in an IRB protocol application. IRB Policy *Section 4.2.*

2. General Information

All investigators must submit an Initial Query or a Full Application through the IRB Protocol Application System (PAS) for human subjects research studies. An Initial Query is a shortened, partial application that may be used to determine if a research study is considered human subjects research or not, if it qualifies as exempt research, or if additional information is required.

It is important that investigators provide a clearly written protocol that conveys sufficient information so that the IRB can evaluate the risks and benefits to the study participants. Pasting information from a grant application is generally insufficient. Investigators should focus on providing a clear, accessible description of what they will do, and ensure that they carefully identify and address the risks and benefits involved with the research. A protocol application includes the following components listed below; however, the IRB Chair, IRB members, or the IRB Administrator acting on their behalf, may request additional materials as needed for review.

3. Training Requirements

Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with elements of the protocol application; however, investigators should carefully read and follow this guidance.

4. Procedure

A. Elements of the Protocol Application

Protocol Applications must include the following elements:

1. The name and contact information for the Principal Investigator (PI) and personnel on the study.

    - All PIs and personnel are subject to the training requirements pursuant to IRB Policy Section 4.6.

    - The IRB may permit minors who are at least 16 years old to work, volunteer or intern in positions that involve the testing of human subjects when certain additional requirements are met. Follow IRB SOP: *Minors Working with the IRB*.

2. A description of participant involvement.

    - A description of participant recruitment and inclusionary criteria, including a description of how participants are recruited (e.g., through advertisements), who participants are (e.g., college students), whether they include vulnerable populations, how many are anticipated (sample size), statistical rationale for sample size. Follow IRB SOP: *Recruitment Materials*.
    - A description of what the participants will experience during the study session. This needs to be in accessible, clear language, and it needs to provide sufficient information so that an IRB member who is not a scientist can understand the protocol (similar to what a participant would expect). The description should include the types of stimuli that might be used, the tasks requested of the participants, and the types of dependent measures collected. Any associated apparatus, device, or equipment for data collection must be described. The nature of the stimuli, tasks, and collected measures must be described in sufficient detail to allow the IRB to evaluate their possible risks, psychological and physical, in relation to the claimed scientific benefits of the study. Copies of questionnaires, surveys or other tools that will be used must be provided.
    - A description of the identifiability of the data. Provide details on the safety and security of identifiable data/specimens where the participant identity may readily be ascertained by the investigator or is associated with the biospecimen. Identifiability is described as follows:

- Identifiable data: Information that identifies the participant are stored in the data set.
- Coded data: Data are considered coded when they meet the following criteria:
  - Identifying information (such as a name or address/location) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
  - A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
- De-identified data: Data are considered de-identified when all direct or indirect identifiers or codes linking the data to the individual participant's identity are destroyed or broken, such that the investigator no longer has the ability to ascertain the identity of the participant.
- Anonymized data: Data is anonymized when the data has been de-identified and the code no longer exists. Anonymization is intended to prevent participant re-identification.
- Anonymous data: No identifying information was collected from the participants. Note that with small participant populations, such as those drawn from the Caltech community, a constellation of characteristics of a population may allow for individuals to be identified and the data may not be anonymous, even when no names or other personally identifying information are collected.

Follow IRB SOP: *Anonymous, De-identified, & Coded Data*.

3. A full description of potential risks to the participants, as well as any benefits, together with a summary of why the investigator believes the benefits outweigh the risks (this includes potential psychological risks, such as emotional distress, physical risks, such as the potential for injury, social, economic, and legal risks. Risks include potential harm, discomfort or inconvenience). The Investigator must explain how these risks compare to those commonly

encountered in everyday life, how the risks will be minimized and how any residual risk is managed and outweighed by societal benefit.

- Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- Greater Than Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are more than minimal risk.

4. When the research is a collaboration with another institution, descriptions of the research activities at each institution, a listing of the roles in the research for each personnel, and a statement as to which IRB(s) will review and approve the research. The application should include, as attachments, any relevant documentation, for example, the collaborator's IRB protocol, informed consent, and approval from the IRB of record or a statement that such approval is in process.

5. When appropriate, a statement that the PI has requested to work with the IRB Office to apply for a Certificate of of Confidentiality (COC) in accordance with NIH provisions, or that a COC has been obtained from NIH.[1] COCs are automatically granted for all NIH-funded studies. Investigators should consider a COC if collecting sensitive information such as drug use, or information regarding civil and/or criminal proceedings, that could potentially be linked to the participants' identity.

6. Confirmation that all investigators involved in the conduct of human subjects research have completed the appropriate human subjects training (CITI or other training as required and approved by the IRB) within the last five years, or within the last three years for clinical trials

[1] Generally, any justified IRB-approved research project may be eligible for a Certificate of Confidentiality from the National Institutes of Health. Federal funding is not a prerequisite for the NIH to issue a Certificate of Confidentiality, but the subject matter of the study must fall within a mission area of the NIH or the Department of Health and Human Services. Under federal law, a COC allows Caltech, the investigators, and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Projects that are NOT eligible for a Certificate are projects that are:

- not research,
- not collecting personally identifiable information,
- not reviewed and approved by the IRB as required by these guidelines, or
- collecting information that, if disclosed, would not significantly harm or damage the participant.

or DOD-sponsored studies. Human subjects training is also required for research that is deemed exempt. The IRB may require investigators to complete new or additional training if there are changes in regulatory requirements or policy. CITI training modules are available at access.caltech.edu, under Research Services – Research Ethics Education (CITI).

7. Identification of the funds used to support the study (funding source and Caltech PTA award number, if available). A single protocol can be supported by multiple non-federal funding sources; however, to ensure compliance with unique federal and Department of Defense (DoD) requirements, work performed on a federal or DoD award should be provided as a stand-alone protocol that applies only to the work with participants funded by the federal or DoD award. See IRB SOP: *Unique Requirements for Work Supported by the Department of Defense (DoD)*.

8. A copy of the Informed Consent Form (ICF) and additional detail as outlined in IRB SOP: *Elements of the Informed Consent*.