PILOT STUDIES	SOP 6.09.01

1. Purpose & Policy

The purpose of this SOP is to provide guidance regarding pilot studies at Caltech. IRB Policy *Section 6.9*.

2. General Information

A pilot study is an initial investigation into the viability of a research project or the refinement of a research project, conducted on a limited scale, typically involving 10 or fewer participants, and characterized by its exploratory nature. Its primary purpose is to assist the investigator in fine-tuning data collection procedures and instruments, or in developing a more refined and precise research design. Compensation is not required for participants of pilot studies. Data from or about participants in a pilot study may not be published and, as such, a pilot study does not contribute to generalizable knowledge, and is therefore not classified as human subjects research. It is important to note that data regarding the design of the research project or instruments, devices or other equipment used in the research, or conclusions obtained from the pilot study (for instance, the stimuli that were chosen for the actual research study), devoid of participant data, is publishable.

When considering a pilot study, Investigators should think carefully and broadly about any potential physical or psychological harms to participants that might be associated with the pilot study. Some examples of potential harms include studies that, when elevated to the level of a proper research study, are greater than minimal risk; or studies where the nature and environment of piloting produces specific risks (e.g., social embarrassment related to sharing of personal ratings, medical information, or results on psychological tests because confidentiality is difficult, if not impossible, in a lab setting). This SOP provides general guidance as to when a pilot study must be reviewed by the Caltech IRB, taking into consideration the types of risks that would require such 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 pilot studies; however, investigators should carefully read and follow this guidance.

4. Procedure

A. Generally, if an investigator plans to publish the human data results collected from or about the participant(s) in the study, it is considered human subjects research and a protocol application is required.

B. Pilot Studies

A pilot study, as defined above in section 2, is an experimental design study that would not contribute to generalizable knowledge and therefore not be considered human subjects research. However, there are certain circumstances where pilot studies require the submission of an IRB Initial Query in the IRB Protocol Application System (PAS). Those circumstances are as follows:

1. Invasive Procedures or Testing of Devices

   If the study involves:

   - employing medical interventions,
   - engaging in medical interactions,
   - invasive procedures,
   - testing of a novel piece of equipment or device, or
   - testing of an FDA or approved device when it is not being used as intended, or operated outside of the normal safety parameters

   on the participant(s), submission of a Query is required.

2. Physical or Psychological Distress

   If the study includes physical or psychological distress, submission of a Query is required. Physical or psychological stressors are of the sort that people would normally choose to avoid in everyday life. A study involving deception, in and of itself, would not be considered problematic unless it causes psychological distress.

3. Vulnerable Populations

   If the study includes:

- minors,
- adults with cognitive impairments, or
- other vulnerable populations,

submission of a Query is required. Vulnerable populations are individuals who are at an increased risk of harm or exploitation due to certain characteristics or circumstances.

4. Sensitive Information Collected from Members of the Caltech Community
   If the study collects sensitive information from Caltech students or lab members, submission of a Query is required. Sensitive information includes physical or medical information, or information that, if discovered could expose the individual to possible criminal or civil prosecution or embarrassment or harassment.

   Typically, the justification for Caltech students or lab members acting as participants in a pilot study is that the overall study will be improved, both scientifically and regarding participant protection. Study parameters, safety and engineering of devices are improved by using pilot participants who are knowledgeable about the equipment and/or experimental methods. It is important to partition the pilot study from the research study.

I'm thinking about setting up a test/pilot experiment that requires input from human participants.

Will you or might you publish* the results collected from or about this person or these people?

Yes/No

Yes → **IRB Review Required Submit Query or Full Application**

No → Will the study involve:
- employing medical interventions
- engaging in medical interactions
- invasive procedures
- testing of a novel piece of equipment or device
- testing an FDA or approved device not being used for its normal purpose
- operating outside of normal parameters on the person or people?

Yes/No

Yes → **IRB Review Required Submit Query**

No → Will the study include physical or psychological distress**?

Yes/No

Yes → **IRB Review Required Submit Query**

No → Will the person or people studied include Caltech students or lab members?

Yes/No

Yes → Will you collect sensitive information*** from the student or lab member?

Yes/No

Yes → **IRB Review Required Submit Query**

No → No IRB Review Required

No → Will the person or people studied include a vulnerable population, or minors, or adults with cognitive impairment?

Yes/No

Yes → **IRB Review Required Submit Query**

No → No IRB Review Required

***Publishing Data** = If an investigator plans to publish the HUMAN data results, it is human subjects research requiring a protocol. If an investigator plans to publish device parameters or other non-human data results, it does not require a protocol.
****Physical or Psychological Distress** = Stressors of the sort that people would normally choose to avoid in everyday life (e.g., excercise for people who are not physically fit, exposing someone who experiences claustrophobia to enclosed spaces such as an MRI, showing disturbing photos)
*****Sensitive Information** = Includes physical or medical information, or information that, if discovered could expose the individual to possible criminal or civil prosecution or embarrassment or harrasment.

IF YOU HAVE QUESTIONS, CONTACT THE IRB AT IRB@CALTECH.EDU

C. Research Studies

Research studies are intended to lead to generalizable knowledge and are often published with data derived from study participants. If a publication presents human participant data as study results in any form (figure, table, or text), this constitutes human subjects research. Note that, if the IRB determines that a proposed pilot study involves research deemed greater than minimal risk, it will no longer be deemed a pilot study, and it will be subject to full IRB research study review and approval.

D. Protocol Application

An Initial Query application should be submitted for pilot studies that include any of the three circumstances outlined above in section 4.A.1-4. Following review of the Query, the IRB may determine that the study constitutes human subjects research and requires the conversion of the Query into a Full Application, or that the study is not human subjects research and can continue as a pilot study. If the study requires submission of a Full Application, the application must be submitted and approved before the study is launched.

E. Study Scenarios:

a. An fMRI study on 3 lab members that explored scanning parameters, sound or video optimization for a subsequent published study in N=50 community-recruited participants.

If imaging data is collected (Section 4.B.4: possible sensitive information) or if the study goes outside of the accepted scanning safety parameters (Section 4.B.1: medical device), this would require a Query and the IRB would deem this to be a pilot study. If no imaging data is collected and the study does not go outside of the accepted scanning safety parameters, this is not human subjects research and does not require a Query.

b. An investigator created a novel device and would like to test it on lab members.

This would require a Query (Section 2.B.1 - a novel piece of equipment or device to be tested). The IRB would deem this to be a pilot study.

c. A PI shows pictures to lab members and they discuss if the pictures might be good stimuli to choose for their study. The group reviews the pictures and raises their hands to vote on which stimuli might be good.

The participant data will not be published, nor is it the subject of the ultimate study. This is not human subjects research nor does it require a Query.

d. An investigator would like to include in the supplementary methods data from a pilot study to determine appropriate sample size and stimulus intensity. An embedded link in the description would link to a graphic of data showing effect sizes vs. stimulus intensity from a pilot sample of 50% women and 50% men who were all native English speakers.

This is a research study requiring IRB review. The participation of human subjects is an integral part of the research, and data are shown. As such, it contributes to generalizable knowledge.

e. A lab is interested in finding a short and easy-to-score IQ test to use for a study, and plan to explore several online IQ tests. They would do this in a lab meeting where lab members take the test in front of other lab members and comment on how easy it was. IQ numbers would be generated and seen by everybody in the lab.

This would require a Query (Section 2.B.2 & 4: lab members, sensitive information, and psychological distress). If the test focused on color discrimination rather than IQ, it would be classified as a pilot study not requiring IRB review. However, in this case, the identifiable sharing of information about IQ tests pose psychological risks and might be uncomfortable or potentially embarrassing for lab members, thus making the study greater than minimal risk and would require IRB review.

5. Informed Consent (IC)

A formal Informed Consent document is not required for pilot studies. However, it is important to inform the pilot study participants that they may elect not to participate in this pilot study, that they may withdraw from the pilot study at any time without any penalty, that their data will not be published, and explain how their data will be used (e.g., to refine the study instrument, data collection procedures). The investigators must have adequate provisions in place to minimize the possibility of coercion.