STUDENTS AND LAB MEMBERS AS STUDY PARTICIPANTS	SOP 4.4.01

1. Purpose

The purpose of this SOP is to provide guidance on conducting research involving Caltech students and lab members as participants. While some of the same considerations may apply to other participant groups (friends, and family members, for instance), this SOP is limited to students and lab members. This SOP does not cover review of studies conducted by undergraduate or graduate students for course credit. IRB Policy *Section 4.4*

2. General Information

Wherever possible, potential research participants should be chosen from a broad base of diverse individuals meeting the inclusion and exclusion criteria for the study. Investigators must not require a student or lab member to participate in research in class or as a condition of employment, and students and lab members should not be selected solely on the basis of convenience.

For purposes of this SOP, “students” includes Caltech students participating in Caltech courses, or students over whom the study investigator has significant authority (e.g. students living in housing where the investigator is a resident advisor). “Lab members” includes all students, postdocs, research and administrative staff, volunteers and visitors, as well as any Caltech personnel supervised by a Caltech investigator or personnel over whom the study investigator has significant authority (e.g. participates on thesis committee).

There are, generally, three categories of studies that might involve students and/or lab members as participants:

(1) Internal Caltech Classroom Studies. Studies in a class where the purpose of the “study” is only to educate the students or inform the Institute. There is no research element of the “study”, i.e. there is no intention of publishing the data for generalizable knowledge. For example, a study in a class to demonstrate how to collect and statistically analyze data or studies conducted by the instructor to inform institute curriculum decisions or the like. While it is not a federal requirement that such studies require IRB review, Caltech policy requires the IRB to review such activities to ensure proper classification of the studies and protection of students.

(2) Laboratory Pilot Studies. Studies in a laboratory are considered "pilot" studies if their purpose is only to optimize the study or actual research experiments. The human subjects data from such studies are not intended to be published as research, although in some cases they may be published as part of the methods of a paper that contains additional research (in which case, they should explicitly be referred to as "pilot data" in the methods of that paper). Typically, the justification for lab personnel acting as participants is that the overall study will be improved, both scientifically and with regard to 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. As with category (1), there is no federal requirement for IRB review of pilot studies, but, again, the Caltech policy requires the IRB to review these studies to ensure proper classification and provide advice to investigators on how best to ensure that ethical issues have been considered.

Investigators should ensure that they have taken the appropriate CITI training and should think carefully and broadly about any potential harms to individuals or to groups, physical or psychological, that might be associated with pilot studies. 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 (for instance, social embarrassment about giving ratings or results on psychological tests when confidentiality is absent in a lab setting).

(3) Research Studies. Studies in classrooms or in laboratories that meet the definition of human subjects research. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (e.g., there is an intent to publish or otherwise disseminate the results from such studies). Research studies would be distinguished from pilot studies (category 2 above) in that every published study is not necessarily a research study, but not every published study includes data from a pilot study. Note that this definition differs from some meanings of "pilot study" – if a published paper only includes data from a "pilot study", then as far as the IRB is concerned, this is actually a research study (category 3) not a pilot study (category 2). Human subjects research is research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated. All human subjects research requires IRB review.

The level of risk to the individuals varies from category to category. While only category (3) requires IRB review under the common rule, Caltech's Charter for the Administrative Committee on the Protection of Human Subjects requires the Caltech IRB to review all categories: 1, 2 and 3, so that appropriate advice can be provide to all PIs. In many cases, category 1 will be quickly deemed "not human subjects research" or "exempt," but the IRB must make this determination, not the PI.

Investigators engaging any of the categories 1, 2 or 3 involving students or lab members should consult with the IRB Chair or Administrator and follow the guidance provided in this SOP. Any questions regarding using students or lab members as participants should be

directed to the IRB at irb@caltech.edu or 626-395-8448 (https://researchcompliance.caltech.edu/research-committees/institutional-review-board)

3. Training Requirements

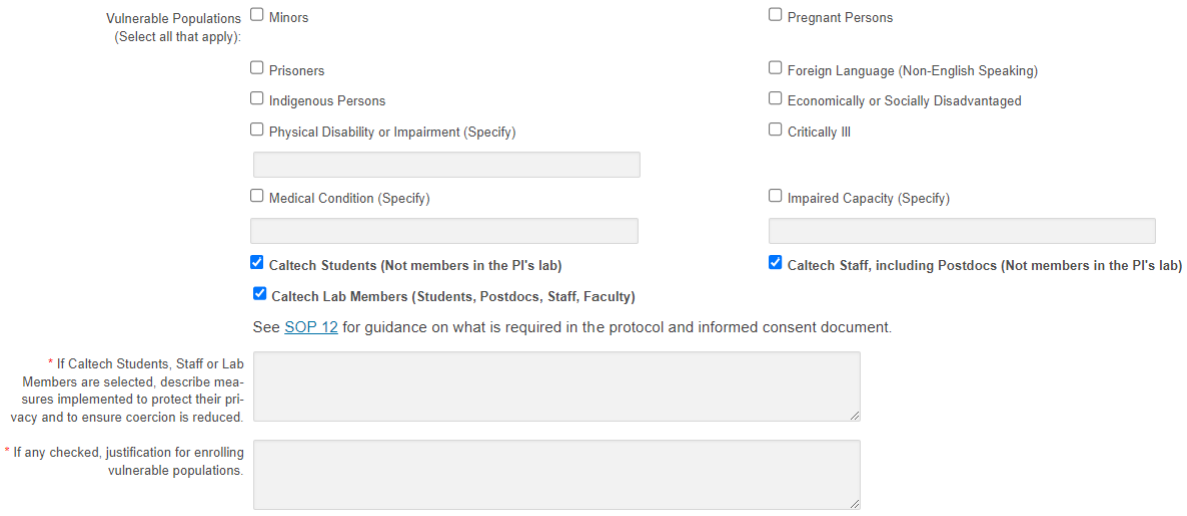
Other than the normally required and study specific training for all human subjects research, there are no specific training requirements associated with students and lab members as research participants; however investigators should carefully read and following this guidance.

4. Procedure

A. IRB Application

Classroom research studies may be exempt (See Exemptions, below). As such, investigators may submit a query for classroom research studies, as applicable. Typically, full protocol applications for studies involving lab members as participants must be submitted for IRB review. A Query is not sufficient.

Caltech students and lab members are classified as vulnerable populations by the IRB. As appropriate, when filling out an online protocol in the IRB system, the investigator should select “Caltech Students”, or if intending for lab members to be participants, select both “Caltech Students” and “Caltech Staff”.



Full Applications are required for all non-exempt Classroom Research Studies, Pilot Studies, and Research Studies using Students or Lab Members. If desired, PIs may initially submit an initial query, and the IRB will inform them if a full application is required.

For Pilot Studies, a full application should be submitted, indicating that the initial application is for a pilot study. The application should also indicate that students and lab members will be recruited as well as the number of such individuals to be included. After approval by the IRB and completion of the Pilot Study, an amendment should be submitted, including changes made to the protocol as a result of the Pilot Study, indicating that the Pilot is

complete, and requesting the number of new participants to be added to the continuing Research Study. If students and lab members will be used for the continuing Research Study, this must be indicated and justification for use of these individuals must be provided.

B. Exemptions

Caltech Students (Educational Settings/Normal Educational Practices):

Research studies using students may qualify for Exemption 1 or Exemption 2 under the common rule. Investigators may submit a query requesting an exemption. Guidance on the exemptions is as follows:

1. Exemption 1. Research studies conducted in a Caltech undergraduate or graduate school class may be deemed exempt from IRB review if they use normal educational practices in an educational setting, provided that the study parameters are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. Examples of studies *not* considered normal educational practices: (a) drug use surveys (the topic is not a normal educational practice), (b) evaluation of a radically new instructional strategy or curriculum, and (c) random assignment of student to different instructional strategies or curricula for comparison. Investigators should submit an IRB query briefly describing their planned classroom study with these classifications in mind.

2. Exemption 2. Research studies with adult Caltech students (18 or older) using an educational test or survey or observing participants' public behavior, may be exempt from IRB review, provided that there is no intervention. Examples of where there is an intervention: (a) assigning some students to take a test in a quiet room vs. noisy room without the students having requested this, (b) giving or not giving students a snack during a test. Research studies with adult Caltech students where an interview is conducted may also be exempt. Investigators should submit an IRB query briefly describing their planned classroom study with these classifications in mind.

Lab Members

All studies using lab members, whether Pilot Studies or Research Studies, should be reviewed by the IRB.

C. Basic Requirements:

Protocol applications will be reviewed by the IRB with regard to the following basic requirements:

Students

The student must meet the inclusion criteria for the study and their confidential information should not be made public in determining whether they meet the inclusion criteria. Students may be recruited for research studies provided that:

(1) the study is minimal risk, there is a prospect of direct benefit to the student, or it is an fMRI study; and

(2) the research is of significant importance, inclusion of the students is justified based upon the merit of the science, and cannot be conducted without the enrollment of these students; and

(3) use of students cannot be out of mere convenience/accessibility to the participant population. That there is no feasible alternative (e.g., no other students outside the researcher's class are available); and

(4) adequate provisions have been made to minimize the possibility of coercion; and

(5) adequate provisions are in place to ensure the student may withdraw at any time without penalty or retribution; and

(6) any institutional data required for the study is obtained according to the Caltech IRB's Institutional Data Use Policy and IRB SOP: *Institutional Data*

Students from within the research investigators' own class should not be recruited. An investigator may request exceptions to these requirements in their IRB protocol. The IRB will consider the requests while reviewing the protocol.

Lab Members

Laboratory Pilot Studies: Lab members may participate in a laboratory pilot study provided that it is a study where data collected are meant to optimize the study participant experimental design or equipment, and provided that the results from the pilot study are not intended to be the main component of a publication (see 2(2) and 2(3) above). For example, an fMRI study on 3 lab members that served to determine the best scanning parameters for a subsequent published study in N=50 community-recruited participants, would be deemed a pilot study. A study of 3 lab members conducted over many fMRI sessions, designed to identify and publish detailed recommendations on the best scanning parameters for neuroimaging, would not be a pilot study, since the survey of scanning parameters is itself the goal of this small-sample research study. Pilot studies may proceed provided that:

(1) the IRB reviewed and approved the activity; and

(2) no confidential or health information about the lab member will be shared with other lab members without consent. Privacy concerns must be addressed in detail in the protocol application and will be carefully considered by the IRB; and

(3) an appropriate informed consent from each lab member must be obtained prior to participation in the pilot study, and appropriate compensation for study participation must be provided; and

(4) there are adequate provisions in place to minimize the possibility of coercion; and

(5) there are assurances that a lab member may refrain from participation altogether or withdraw at any time without penalty or retribution.

A researcher may request that an exception to these requirements be made. The IRB will consider such requests on a case-by-case basis.

Research Studies: Generally, potential participants should be chosen from a broad base of individuals meeting the criteria, rather than from individuals who report directly to the investigator. A lab member participant must meet the inclusion criteria for the study and their confidential information should not be made public in determining whether they meet the inclusion criteria. Lab members may be recruited from within one's own lab for research studies provided that:

(1) the study is minimal risk or there is a prospect of direct benefit to the lab member (in this instance, the Caltech IRB may consider fMRI studies to qualify as "minimal risk"); and

(2) the research is of significant importance, inclusion of the lab members is justified based upon the merit of the science, and cannot be conducted without the enrollment of these lab members. Use of lab members cannot be out of mere convenience/accessibility to the participant population; and

(3) adequate provisions have been made to minimize the possibility of coercion; and

(4) adequate provisions are in place to ensure confidentiality; and

(5) adequate provisions are in place to ensure that the lab member may withdraw at any time without penalty or retribution; and

(6) any institutional data required for the study is obtained according to the Caltech IRB's institutional data use policy.

A researcher may request that an exception to these requirements be made. The IRB will consider such requests on a case-by-case basis.

D. Recruitment

In the protocol application, investigators must describe incentives and recruitment materials and how those incentives and materials are designed to minimize coercion and preserve privacy of students or lab members.

Students

Incentives: Students should not be required to participate in research (without a comparable non-research alternative offered) as a course requirement or for extra credit.

Alternatives to participating in research for course credit or extra credit must be comparable in terms of time, effort, and fulfillment of course requirements. If payment is offered, credit for payment should accrue as the study progresses- it may not be contingent on completing the entire study.

Recruitment Materials: Investigators should not recruit students through direct interaction and should have a recruitment mechanism that allows students to opt-in anonymously. Students should not be recruited from an investigator's own class. The recruitment of students should be through general announcements, postings, sign-up sheets, or other methods that require an interested student to initiate contact with the investigator.

Lab Members

Incentives: Lab members must not be required to participate in research as a condition of employment. A lab member's decision to participate may not affect performance evaluations, career advancement, or other employment-related decisions. When regular workplace activities are the topic of research, investigators must clarify for potential research participants those activities that are optional and distinct from required workplace activities. As applicable, lab members are entitled to the same incentives as non-lab member participants. If payment is offered, credit for payment should accrue as the study progresses- it may not be contingent on completing the entire study.

Recruitment Materials: Recruitment of lab members should be achieved through a broad announcement about the study sent to all lab members and, when feasible, other lab groups via email. If possible, such announcements should be sent by a laboratory administrator and not by the PI or researcher. Alternatively, announcements may be made in lab meetings. Recruitment materials should be in accordance with IRB SOP: *Recruitment Materials.*

Investigators should not recruit students through direct interaction and should have a recruitment mechanism that allows students to opt-in anonymously.

E. Risks

The researcher should include a listing of the risks to students or lab members in the "Risks and Benefits" section of the protocol application. Risks must be conveyed to the participants in the Informed Consent

1. Voluntary Nature

   There is an inherent risk that a student or lab member may feel pressure to participate in a class study or in a research project in their laboratory. Investigators should recognize that such pressure can be perceived to come from the instructor or PI or from classmates or lab mates, even when there is no intention. Students and lab members must not be compelled to participate in research as part of a course requirement or their employment/inclusion in a laboratory. The study should include

a plan regarding recruitment, incentives, minimization of risks, and appropriate withdrawal measures, to ensure that students and lab members know that they may choose not to participate in the research and that their decision will not affect their grade, class standing, career advancement, employment, or relationship with the researcher who is also their instructor/advisor/supervisor.

If at all possible, a third party (not the instructor of a class or the PI or other lab member) should recruit, consent, collect data, and/or be available for consultation or to ask for withdrawal from the study.

2. Non-Physical Risks

There is increased risk of non-physical harm in a classroom or work environment, especially where classmates or lab members may be able to identify study participants. All such non-physical risks must be identified for a study with a plan to minimize and disclose those risks to participants.

a. Reputational harm

b. Risk of privacy or confidentiality

c. Impact on learning or work environment

Many of these non-physical risks can be mitigated if the investigators are blinded to the identity of a participant (may require an independent party to collect data). If the research is conducted within a classroom setting, the instructor should be blinded to the identity of participants, at least until grades are posted. It may help to minimize the above risks by ensuring that a diversity of lab members are required for pilot studies, rather than only a few of them over and over again.

F. Informed Consent:

1. Investigators must obtain informed consent, consistent with Caltech IRB policies. Ideally, the recruitment and/or consent process should be conducted by someone who does NOT have any authority or influence over the potential participants. The third party may be an individual from the department office, another faculty member, or a co-investigator who has no relationship to students in the class or the lab members.

2. Type of consent:

a. Assent: If minor students or lab members are participating in a research study, minor participant assent and parental consent must be obtained. The IRB may consider and grant a waiver of signed consent, if appropriate. In either event, the consent must be obtained and documented prior to collecting data from minor participants.

b. Notification: If the IRB finds that a waiver of consent (or parental permission, for minor participants) is appropriate and permissible, notification to participants (or

parents, if minor participants) must be provided, with an option to opt out of the study.

c. Consent: Typically written informed consent will be required when students or lab members are participants in a research study conducted in their instructor's class or in their advisor's lab. Elements and language required in the informed consent is provided in this SOP (see 4, below).

3. Who obtains consent?

   Students and lab members can be vulnerable to feeling pressured to participate in research, either by their peers or by the person obtaining consent. Students and lab members may be concerned that choosing not to participate may jeopardize their relationship with their instructor, advisor or supervisor. Ideally, the recruitment and/or consent process should be conducted by someone who does NOT have a status relationship with the potential participants. If at all possible, classmates or lab mates should not be charged with obtaining consent.

4. Informed Consent Language

   In addition to a description of all risks, physical and non-physical, the following language must be included in the informed consent:

   If you are participating in this research because you are in a class offered by the investigators, or work in the same lab as the investigators, or are supervised by the PI or one of the investigators, it is important that you understand that your participation is still entirely voluntary; you have the right to decline. If you think that you are being unduly pressured to participate, or that you will be penalized in some way for non-participation, please contact the Institutional Review Board (IRB) that is tasked with protecting human subjects at 626-395-8448 or irb@caltech.edu.