| MINORS WORKING WITH THE IRB | SOP 4.2.01 |
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## 1. Purpose & Policy

The purpose of this SOP is to provide guidance on minors who observe, work, volunteer, or intern in positions that involve human subjects research. IRB Policy *Section 4.2*.

## 2. General Information

A minor is any person under the age of 18 years. The IRB permits minors who are at least 16 years old to observe, work, volunteer, or intern in positions that involve human subjects research when certain additional requirements are met. For researchers who are minors under 16 years of age, the IRB will consider each protocol on a case-by-case basis and may approve such minors to perform data analysis on participant data, with participant consent.

Under the provisions of state and federal law, as well as Caltech's Minors Personnel Memorandum ("Minors PM") and Caltech's Standards for Working with Minors (Standards), minors may not be employed, intern or volunteer in any hazardous occupations.

Pursuant to the Minors PM, minors observing, working, interning or volunteering in laboratories must be approved by the Division Chair, or designee, in consultation with the supervising Principal Investigator (PI). Minors working in areas with restricted access must also be approved by the supervising Director. Minors working with regulated subjects or materials must obtain the permission of the appropriate Caltech administrative committee.

PIs must obtain IRB protocol approval before minors can observe, work, intern or volunteer in positions that involve human subjects research.

## 3. Training Requirements

In addition to the required human subjects research training, all Caltech personnel who interact with minors involved in human subjects work must adhere to the proper standards outlined in Caltech's Standards. Investigators should also carefully read and follow this guidance.

## 4. Procedure

Minors who are registered at Caltech as workers, volunteers, or interns may analyze human subjects data, and under certain circumstances, observe participants under an approved IRB protocol. PIs that would like to have minors observe, interact with and/or collect data from participants must indicate that the researcher is a minor in their submitted protocol(s). Minors may not participate in any human subjects work without prior IRB protocol approval.

A. **Minor Workers, Volunteers & Interns**

Minors are only allowed to help administer research protocols that do not require special licenses or skills (e.g., they cannot drive a car, and no one under 21 can serve alcohol), and they may only administer protocols that are exempt or are, at most, deemed to be minimal risk by the IRB. They may not operate equipment that could, in the opinion of the IRB, pose significant physical risks (e.g., operating a magnetic resonance imaging (MRI) scanner or an experimental device).

Minors may only interact with and collect data from participants under the supervision and responsibility of an adult researcher ("supervisor"). The supervisor or at least one other adult (other than the participant) must be present in the research suite when a minor is collecting data from the participant. The supervisor must take responsibility for the study, train the minor in how to interact with participants, how to carry out the study session, and be available to answer any questions as they arise.

Minors may not administer informed consent, although they may be present during the informed consent process. It is recommended that the supervisor, after having obtained informed consent, introduce the participant and the minor and explain the nature of the study, before letting the minor take over to collect the data.

B. **Minor Observers**

PIs must identify a research escort for each minor observer. Minor observers must be accompanied by and be under the direct supervision of their escort at all times during their visit. Observers are not permitted to interact with or collect data from participants, although the participant must be informed of the observer's presence and their role.

The IRB has discretion to define the timing and scope of each observer's visit.

**5. Informed Consent**

The Informed Consent document must inform participants that minors may be present in the study as observers, workers, interns, or volunteers, and it should specify the roles these minors will undertake.