CalARTS

IRB Guidelines and Definitions

Principal Investigator & Other Personnel

The **principal investigator (PI)** is the individual with whom the IRB will primarily be in contact with over the course of the protocol review and approval process. The PI is usually the lead on the research team, but may also be a faculty member supervising student research. If the study is part of an equal partnership, select one co-investigator as PI for administrative functions and select "Co-PI" as the role for the other members of the partnership.

An **investigator** not listed as a primary investigator or co-PI is an individual actively involved in conducting the research through the collection or analysis of data. Use the role of **key personnel** to identify other individuals who are providing assistance to the study while not taking an active role in the collection or analysis of data. Another way of thinking about whether to categorize someone as an investigator or as key personnel is whether or not the individual is expected to be an author on the scholarship that would result from the study.

Review Type

When selecting a review type, review the definitions below, keeping in mind that these definitions are not comprehensive. If a member of the IRB believes the study should be reviewed at a different level, they will inform the PI and ask for additional information if needed.

An **exempt** study, despite its name, must still be reviewed and approved by the IRB. To qualify as an exempt study, the following must apply:

- The study must pose no more than minimal risk to participants.
- The study cannot recruit participants from vulnerable populations, except in the case of educational settings or tests for individuals under the age of 18.
- The study must not include identifiable information on the participants, nor may it involve video or audio recording on the participants

Expedited studies require a more thorough review than exempt studies due to not meeting one of the qualifications above, but still pose no more than minimal risk to participants.

Full Board studies pose more than minimal risk to participants. In addition to PIs needing to more thoroughly describe the purpose, risk, benefits, and necessary precautions for the study, the full IRB board must review and approve the protocol, which will lengthen the time to approval. These studies must also go through yearly continuing review so long as the investigators are still in contact with the participants.

Minimal Risk

Federal regulations define **minimal risk** as meaning "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." (45 CFR 46.102)

Informed Consent

The most thorough method of obtaining informed consent is through an informed consent statement signed by the participant. Other methods may include verbal assent or the provision of the elements of informed consent in the invitation or first page of a survey. The basic elements of informed consent are described in the informed consent statement template.

Informed consent can be altered or waived if the study poses no more than minimal risk, if the study could not be practically carried out without the waiver or alteration, and if the waiver or alteration will not adversely affect the rights and welfare of the participants.

Ensuring Participant Safety

The most thorough method of obtaining informed consent is through an informed consent statement signed by the participant. Other methods may include verbal assent or the provision of the elements of informed consent in the invitation or first page of a survey. The basic elements of informed consent are described in the informed consent statement template.

Informed consent can be altered or waived if the study poses no more than minimal risk, if the study could not be practically carried out without the waiver or alteration, and if the waiver or alteration will not adversely affect the rights and welfare of the participants.

Training Requirements

Due to financial constraints, formal human subjects research training with certification is not presently available to investigators. In place of such training, the principal investigator, co-PIs, and other investigators who have not received certified training elsewhere in the past three years must read chapters 1 through 4 as well as chapter 8 in *Teaching the Responsible Conduct of Research in Humans*, available online through the Health and Human Services website in addition to *The Belmont Report*.

Conflicts of Interest

All personnel involved in a study must disclose whether they have any significant financial interests related to the study. Indicate for each investigator or key personnel member whether they have any of the following financial interests that might be associated with the study:

- Salary
- Commissions or consulting fees
- Royalties
- Business ownership
- Capital gains
- Intellectual property rights

Disclosing conflicts of interest will not necessarily result in a rejection of the protocol, but are a way to protect the integrity of the study by acknowledging such considerations prior to the commencement of the study