

UCSF Human Research Protection Program

Responsibilities for Research Involving Human Subjects Information Sheet for Principal Investigators

THE PRINCIPAL INVESTIGATOR (PI) IS ULTIMATELY RESPONSIBLE FOR ALL ASPECTS OF CONDUCTING THE RESEARCH STUDY, including the supervising of all staff to whom study responsibilities are delegated (e.g., clinical research coordinators). While the PI may delegate responsibilities as appropriate, it is the PI who is responsible for ensuring that all research activities are carried out correctly.

The PI must be qualified by education and training in the therapeutic area in which the research is being conducted. The PI must be familiar with the protocol and investigational articles being tested and must also comply with the applicable regulatory requirements [Code of Federal Regulations](#), [FDA Good Clinical Practice \(GCP\)](#) and [International Conference on Harmonization \(ICH GCP Guidelines\)](#), state laws and [institutional policies and guidelines](#).

PIs are responsible for:

PROTECTING THE SAFETY AND WELFARE OF RESEARCH PARTICIPANTS

- ✓ Conducting the study in an ethical manner, including protecting the rights and welfare of human subjects who are involved in the research project.
- ✓ Ensuring that the resources necessary to protect participants are present before conducting the research study.
- ✓ Reporting unexpected or serious adverse events to the CHR according to the UCSF Human Research Protection Program (HRPP) [Adverse Event Reporting Guidance](#).
- ✓ Reporting protocol violations and research-related incidents to the CHR according to the UCSF HRPP [Reporting Violations and Incidents in Research Protocols Guidance](#).
- ✓ Reporting any correspondence to or from a regulatory agency regarding matters of regulatory compliance (e.g., FDA audit findings, PI audit response letter) to the CHR.
- ✓ Responding to [participants' complaints/concerns](#) or requests for information and [reporting](#) to the CHR any significant [participant complaints/concerns](#).
- ✓ Designing and carrying out the research study with adequate [data and safety monitoring](#), when appropriate.
- ✓ Assuring that the [protected health information \(PHI\)](#) requested, if any, is the minimum necessary to meet the research objectives, and that PHI is not reused or disclosed to any parties other than those described in the CHR-approved protocol, except as required by law.

TRAINING AND SUPERVISING COLLABORATING FACULTY AND STAFF

- ✓ Ensuring that all participating faculty and research staff observe pertinent laws, regulations, and institutional policies and guidelines.
- ✓ Ensuring that [key personnel](#) performing the study are qualified, appropriately trained or re-trained and adhere to the provisions of the CHR-approved protocol.

ADHERENCE TO REGULATORY AND CHR REQUIREMENTS AND GUIDANCE

- ✓ Completing [CHR-required human subjects protection training](#) (in addition to other sponsor-required training).
- ✓ Ensuring that all research involving human subjects receives [CHR review and approval](#) before commencement of the research, including screening or recruitment.
- ✓ Seeking [CHR guidance](#) when in doubt about whether proposed research requires CHR review.
- ✓ Complying with all CHR decisions, conditions, and requirements.
- ✓ Obtaining CHR review and approval before changes are made to approved protocols or consent forms ([CHR modification request](#)).
- ✓ Ensuring that no human subject is involved in the research prior to obtaining his or her consent.
- ✓ Ensuring the adequacy of the [informed consent process](#).
- ✓ Ensuring that protocols receive at least yearly [continuing CHR review](#) and approval.
- ✓ Providing financial disclosure information or any other potential conflicts of interest that might affect the relationship with the research participant or the outcome of the research.