



Guidance and Procedure: Investigator Responsibilities for Research Involving Human Subjects (last updated June 9, 2016)

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Qualifications to Serve as Principal Investigator

As described in [UCLA Policy 991: Protection of Human Subjects in Research](#), the UCLA IRBs perform IRB review for all faculty and staff who are conducting studies involving Human Subjects within the course and scope of their duties, as well as UCLA students who are conducting studies involving human subjects within the course of their studies.

UCLA faculty and staff researchers must meet the criteria for “Principal Investigator” outlined in [UCLA Policy 900: Principal Investigator Eligibility](#), or obtain an Exception as described in Policy 900 Section III(C).

UCLA student researchers must have a Policy 900-qualified faculty sponsor.

General Responsibilities of Principal Investigators

This guidance document describes UCLA Principal Investigator (PI) responsibilities related to the conduct of human subject research.

The PI ultimately is responsible for all aspects of conduct of the research study, including the supervision of all co-investigators and research personnel to whom study responsibilities might be delegated. While the PI may delegate responsibilities as appropriate, the PI is responsible for ensuring that all research activities are designed and performed in an ethical manner and in accordance with the IRB approved protocol application.

The PI must be qualified by education, training and experience in the area in which the research is being conducted. The PI must be familiar with the IRB approved protocol, all applicable regulations and guidelines, state laws, and institutional policies and guidelines pertaining to his or her human research and clinical investigations (see *References* below).

Responsibilities for Protecting the Rights, Safety and Welfare of Research Participants

- Design research studies that will most likely develop or contribute to generalizable knowledge, while ***minimizing risks and maximizing benefits***.
- Conduct the study in an ethical manner, including ***protecting the rights and welfare of human subjects*** who are participants in the research study.
- Ensure ***fair and equitable recruitment practices*** and avoid recruitment practices that place participants at risk for coercion or undue influence.
- Obtain the ***legally effective consent*** of the participant or the participant's legally authorized representative (when IRB approved) prior to participation in research.
- ***Ensure adequate resources*** (e.g., personnel, time, facilities, funding, access to a study population) to conduct the research in a way that will protect the rights and welfare of participants and ensure the integrity of the research.
- Design and carry out the research with ***adequate data and safety monitoring***, when appropriate.
- ***Respond promptly to participants' complaints*** and/or concerns or requests for information and report to the IRB any significant **Complaints and Concerns Regarding the Conduct of Human Subjects Research**
- ***Assure that the Protected Health Information (PHI)*** created or used in the research study, 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 IRB-approved protocol, except as required by law.
- ***Report promptly*** unexpected or serious adverse events, protocol violations, deviations, incidents and complaints to the IRB according to **Post Approval Reporting** guidance.
- ***Report promptly*** updated study safety information to and from regulatory agencies (e.g., audit findings, PI audit response letters) according to the **Post Approval Reporting** guidance.

Responsibilities for Adhering to Regulatory, Institutional and IRB Requirements

- Seek **OHRPP guidance** when uncertain about whether proposed activities require IRB review.
- Complete required **CITI on-line training** as well as other sponsor-required training.
- Complete required **UCLA Health System HIPAA Privacy and Information Security Training for New Workforce Members**, when applicable.

- Ensure that all [human subjects research](#) receives IRB review and approval prior to commencement, including screening and/or recruitment.
- Ensure the consent process meets the criteria for legally effective informed consent and documentation of the [informed consent process](#), as approved by the IRB.
- Provide a copy of the [State of California Participant's Bill of Rights](#) (for medical research) to each subject in his or her preferred language during the consent process, unless waived by the IRB.
- Ensure that protocols receive [continuing IRB review](#) and approval prior to the expiration date stated on the approval notice and in webIRB (usually within one year).
- For those protocols where UCLA is relying on an external IRB, maintain a current reliance registration in webIRB.
- Provide [disclosure of financial interests](#) information and disclosing any other potential conflicts of interest that might affect the relationship with the research participant or the research outcome.
- Comply with all IRB determinations, conditions, and requirements.
- Obtain IRB review and approval *before* changes are made to approved protocols or consent forms according to the [Amendments to Previously Approved Research](#) guidance.
- Obtain approvals from [other institutional entities](#), when applicable (e.g., ISPRC, MRSC, ESCRO, IBC, RDRC).
- Comply with IRB [Study Closure](#) requirements.

Responsibilities for Training and Supervision of Participating Faculty and Staff

Ensure that all participating faculty and research staff:

- Observe applicable laws, regulations, and institutional policies and guidelines.
- Are qualified and appropriately trained for their roles and responsibilities and adhere to the provisions of the IRB-approved protocol.
- Complete CITI human subjects protection on-line training.
- Complete UCLA HIPAA research training, when applicable.

Responsibilities for Research Recordkeeping

- Maintain records of all approved-IRB documents and correspondence which must include at minimum the IRB application, sponsor protocol (if applicable), screening, recruitment and

consent documents, data collection materials and instruments, documentation of subject eligibility and participation and a copy of all signed consent forms unless waived by the IRB.

- Retain all study records for a minimum of three years past the close of the study, a minimum of six years for studies involving PHI, and any other sponsor requirements.
- Retain records for studies involving FDA regulated test articles (drugs, devices, biologics) in accordance with applicable FDA regulations.
- Make all research records accessible for review by authorized representatives of the IRB and/or the department or agency supporting or conducting the research to ensure proper performance of the study and compliance with federal regulations and institutional policies
- Maintain confidentiality of stored records in accordance with the IRB-approved protocol.

References and Regulations

- [DHHS OHRP Investigator Responsibilities – FAQs](#)
- [FDA Regulations Related to Good Clinical Practices and Clinical Trials](#)
- [FDA: Investigator Responsibilities](#) (2009)

Change history:

6/9/2016: Reworded continuing review responsibility to account for possibility of extended approval and for reliance on external review; updated links.