

Policy Number: 61

Title: Investigator Responsibilities

Date of Last Revision: July 27, 2007

I. Introduction

The university, investigators and their research staff, and the IRBs/OPRS, share the collective responsibility for the ethical conduct of research.

Investigators are required to obtain prospective UCLA IRB review and approval or certification of exemption from IRB review for all *human subjects research*¹ activities conducted for which:

- (1) the conduct or recruitment of the research involves UCLA resources (property, facility or funding, including extramural funds administered by UCLA);
- (2) the research is conducted by or under the direction of any employee, student or agent of UCLA in connection with his or her institutional responsibilities;
- (3) the research is conducted by or under the direction of any employee, student or agent of UCLA using any property or facility of UCLA; or
- (4) the research involves the use of UCLA's non-public information to identify or contact human research subjects or prospective subjects.

Investigators who transfer research to UCLA from their previous institution are required to submit the project to the IRBs for review and approval in order to continue the study.

Investigators conducting research at another institution who become affiliated with UCLA and will continue to be involved in the research at the other institution, are required to submit the project to the IRBs for review and approval in order to continue to be involved in the research.

II. General Investigator Responsibilities

- A. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the UCLA Federalwide Assurance (FWA).²

¹ Please see [OPRS/IRB Policy 3: Human Subject Research Determinations](#).

² <http://oprs.ucla.edu/human/manual/hspcmanual/FWA>

- B. Research investigators who intend to involve human research subjects will not make the final determination of exemption from applicable Federal regulations or provisions of the UCLA FWA.
- C. Research investigators are responsible for providing a copy of the IRB approved and IRB stamped informed consent document and the State of California Subject's Bill of Rights (for medical research) to each subject during the consent process, unless the IRB has specifically waived these requirements. All signed consent documents are to be retained in a manner approved by the IRBs.
- D. Research investigators are responsible for adhering to the IRB approved protocol as well as the approved informed consent procedures and will promptly report proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects. Changes made to eliminate apparent immediate hazards to research subjects must be reported to the IRBs promptly in accordance with established IRB procedures.
- E. Research investigators are responsible for reporting progress of approved research to the OPRS, as often as and in the manner prescribed by the approving IRB on the basis of risks to subjects, but no less than once per year.
- F. Research investigators will promptly report to the IRB within 10 days any injuries or other unanticipated problems involving risks to subjects and others.
- G. No research investigator who is obligated by the provisions of the UCLA FWA, any associated Inter-Institutional Amendment, or Noninstitutional Investigator Agreement will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law. However, such activities will not be counted as research nor the data used in support of research.
- H. Research investigators will advise the IRB, OPRS and the appropriate officials of other institutions of the intent to admit human subjects who are involved in research protocols for which the UCLA FWA or any related Inter-Institutional Amendment or Noninstitutional Investigator Agreement applies. When such admission is planned or a frequent occurrence, those institutions must possess an applicable OHRP-approved Assurance prior to involvement of such persons as human subjects in those research protocols.
- I. Research investigators will maintain research records and arrange access for their inspection as required by applicable regulations and IRB policies. This responsibility continues even if the investigator leaves UCLA.

- J. Research investigators must meet the requirements outlined in the UCLA Policy 900: Principal Investigator Eligibility, in order to serve as "Principal Investigator" for a study.
- K. Research investigators must meet the requirements outlined in the UCLA Policy 900: Principal Investigator Eligibility, in order to serve as "Faculty Sponsor" for a UCLA student who is acting as "Principal Investigator" for a study.

III. Research Files

Investigators are required to maintain a research file. The requirements for a research file include but are not limited to, all correspondence with the IRB and the sponsor (as applicable), and documentation of subject eligibility as well as a copy of the signed consent forms obtained from all subjects participating in and/or who have participated in the protocol regardless of whether or not the subjects completed the study. The protocol files should also contain any data derived from the study. This file will act as the investigator's documentation regarding the proper performance of the study. This information may be reviewed by the IRB, federal, State or local authorities, sponsors, and other authorized individuals to ensure proper performance of the study. These rules also apply to student researchers, even after graduation

For medically invasive studies involving patients as research subjects, the investigator should ensure that a copy of the IRB approved consent form, signed by the subject or his/her legal representative, is inserted into each subject's medical record.

The investigator is responsible for ensuring that a copy of the consent form is provided to each subject enrolled in the study.

IV. Record Retention

UCLA policy requires that investigators maintain research records for at least three years after completion of the research, whether or not the research is federally funded. Additional requirements for record retention vary with the type of research conducted and provisions of the investigator's funding source. The IRB highly recommends that investigators clearly understand the retention requirements of their sponsor. The IRB encourages investigators to maintain research records for longer periods, if practicable.

The conditions for maintaining confidentiality of the subjects and the research records are required for the life of the data. These rules apply equally to research conducted by students and faculty.

All records must be accessible for inspection and copying by authorized representatives of the IRB, department or agency supporting or conducting the research at reasonable times and in a reasonable manner.

Protocols conducted with FDA regulated articles must be kept in accordance with current FDA regulations. Current FDA policy states that investigators are required to maintain records for the longest of either:³

- (1) A period of at least two years following the date on which the results of the clinical investigation are submitted to the FDA in support of an application for a research Investigational New Drug Number or Investigational Device Exemption or marketing permit; or
- (2) A period of at least two years following the date on which an application for research or marketing permit (in support of which the results of the clinical investigation were submitted to the FDA) is approved by the FDA; or
- (3) Two years after the investigation is discontinued and FDA is notified of that fact.

V. Confidentiality

Investigators are required to maintain and protect the privacy and confidentiality of all personally identifiable information of all human subjects participating in research, except as required by law or released with the written permission of the subject. Subjects, including children, have the right to be protected against invasion of their privacy, to expect that their personal dignity will be maintained, and that the confidentiality of private information will be preserved. The more sensitive the research material, the greater the care required in obtaining, handling, and storing the data.

Information through which subjects may be identified include their names, student identification numbers, hospital ID numbers, social security numbers, driver's license numbers, home addresses, photographs, and videotapes. Individuals also may be identified by description, for example, as the personnel manager in a particular company, the sixth grade teacher in a certain school, or the pediatric nurse at a local hospital. If information or data to be collected can be traced back to individual subjects, safeguards should be provided to ensure confidentiality.

VI. Reporting Adverse Events, Complications, Complaints and Unanticipated Problems

UCLA investigators are responsible for reporting to the IRB any occurrence under the following policies:

- [*OPRS/IRB Policy 15: Biomedical Adverse Event Reporting*](#)
- [*OPRS/IRB Policy 53: Noncompliance*](#)
- [*OPRS/IRB Policy 55: Protocol Violations*](#)
- [*OPRS/IRB Policy 56: Incident Reporting*](#)
- [*OPRS/IRB Policy 57: Unanticipated Problems Involving Risks to Subjects or Others*](#)

³ 21 CFR 312.57 and 21 CFR 312.62

- [OPRS/IRB Policy 58: Subject Complaints](#)

VII. Closing Studies

When the conduct of a study at UCLA ends, whether because the study has been terminated or completed (including data analysis), or because the principal investigator terminates employment or other association with UCLA, the principal investigator must submit a final report (Form HS-8) to the IRB (unless a new principal investigator is identified to continue the study). The HS-8 is available on the “Forms” page of the OPRS website. For additional information, see *OPRS/IRB Policy 17: Study Closure*.

Final Reports are required because of the serious risks to research subjects that may arise when research activities are terminated without IRB knowledge. For example, if a study is closed or IRB approval has lapsed, then ethically or medically indicated follow-up procedures may not be available. Research activities may be closed by the IRB without investigator approval if it is determined that the investigator is no longer affiliated with UCLA.

VIII. Conflicts of Interest

The IRBs require that investigators disclose within their application all financial interests related to the study. The IRB may require disclosure of conflicts of interest in consent forms and other mechanisms for minimizing conflicts, including referral for review by the institution. When investigators are also the treating physicians for subjects, the IRB is also concerned with the potential conflict between those two roles. University policy requires disclosure of that second conflict using standard language available in consent form templates available on the OPRS website. See [OPRS/IRB Policy 63: Investigator Financial Interests and Conflicts of Interest](#).

Regulations:

21 CFR 56.109, 56.111

21 CFR 54

45 CFR 46.109, 46.111

Reference:

State of California Subject’s Bill of Rights

Attachment:

UCLA-3 UCLA Policy 900: Principal Investigator Eligibility