

UC Davis Policy and Procedure Manual

Chapter 240, Research Integrity

Section 57, Responsibilities of Researchers and Others After Protocol Approval

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Supersedes: New

Responsible Department: Office of Research

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Responsibilities of Investigators

All investigators have primary ongoing responsibility for the health and well-being of subjects. Each investigator must respect the rights of subjects to be treated with dignity, respect, justice, and the intent not to harm throughout the research study.

Significant New Findings

Investigators are to provide the subject with significant new findings developed during the course of the research that may affect that subject's willingness to participate.

- If harm to the subject could result from suddenly withdrawing from the study, such information must be given to the subject.

Unanticipated Risks or Harm

If the investigator becomes aware of unanticipated risks, adverse effects, or harm to a subject or others, the investigator must immediately inform the subject and the Human Subjects Review Committee (HSRC). The Vice Chancellor--Research or the HSRC may require that the activity be suspended until an assessment of those risks or adverse effects can be made and a decision whether or not to continue the activity has been made. The reasons for suspension are provided to the investigator and to the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) if the project is sponsored by HHS or subject to regulation by FDA.

- If necessary, alternative care and/or medication must be provided to the subject in the interim.
- FDA regulations must be observed if an investigational drug or device is involved.
- Hospital reporting requirements must be observed.
- For specific UCDCM requirements, refer to the UCDCM Hospital Policies & Procedures Manual.

Monitoring Activities

The HSRC may monitor studies at its discretion. Monitoring may take the form of outside observation of various aspects of the study, reporting requirements during the course of the study, or other actions as appropriate. The HSRC has the authority to observe or have a third party observe the consent process and the research. The investigator must ensure that monitoring activities are accomplished or cooperate as required.

Complaints of Subjects or Others

If subjects or others have questions or complaints about research protocols, the HSRC will investigate and recommend appropriate action to the Vice Chancellor--Research. This also applies to activities that have not, but should have, undergone HSRC review.

- Complaints may be stated anonymously, but formal action requires identification of the complainant.
- The HSRC or Vice Chancellor--Research may require curtailment or suspension of activities until an investigation has been completed.
- The investigator may be required to modify the protocol to eliminate an identified problem,

or the activity may be terminated.

Noncompliance with HSRC Requirements

The HSRC is required to report any serious or continuing noncompliance with HSRC requirements to the Vice Chancellor--Research.

- On recommendation of the HSRC, the Vice Chancellor--Research will require suspension, termination, or curtailment of the activities.
- The Vice Chancellor--Research must report such noncompliance to the Office for Protection from Research Risks, HHS.

Record Retention

The Office of Research is the office of record for human subjects protocols.

- Copies of executed consent forms must be retained in departmental files for three years after completion of the study or three years after the age of majority of minor subjects, whichever is later.
- Executed consent forms must be retained in UCDCMC patients' medical record files.