Chapter 240, Research Involving Human Subjects
Section 50, General Policy Regarding Human Research
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Responsible Department: Institutional Review Board Administration
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I. Purpose

This section describes the policies governing human research, including the oversight authority and responsibilities of the Institutional Review Board (IRB), and the responsibilities and requirements of Investigators engaged in human research.

II. Definition

Human subjects research—any research project that obtains data about the subjects of the research through intervention or interaction with them; identifiable private information about the subjects of the research; or the informed consent of human subjects for the research.

III. Policy

A. UC Davis is committed to the protection of human subjects used in any research study.

B. The IRB must review, approve, and maintain appropriate records for all human subjects research that is conducted or sponsored by the University.

C. Members of the IRB, IRB administrative staff, the organizational official, PIs, and research staff are guided by the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report) and all Federal, State, and local requirements for protecting research participants.

D. Human subjects research that is sponsored by a federal department or agency is subject to any additional regulations as required by that agency (see Investigator Manual, HRP-103).

E. Payments to professionals in exchange for referrals of potential subjects, or payments designed to accelerate recruitment that are tied to the rate or timing of enrollment are prohibited.

IV. Roles and Responsibilities

A. Investigators:

1. Complete the appropriate training and ensure all research staff completes appropriate training as described in the Investigator Manual.
2. Seek appropriate approval for any human subjects research prior to commencing research.
3. Secure appropriate consent from human subjects.
4. Maintain required records of human subjects research activities.
5. Comply with all determinations and requirements of the IRB, the Organizational Official, and the sponsoring agency.

B. Organizational Official (Vice Chancellor—Research or designee):

1. Appoints IRB chairs and members.
2. Oversees the review and conduct of human subjects research under the jurisdiction of the Human Research Protection Program, including limiting, suspending, terminating, or

disapproving research approved by the IRB (see Human Research Protection Program Plan, HRP-101).

3. Ensures that the research review process is independent and free of coercion or undue influence.
4. Receives and acts on complaints or allegations of wrongdoing related to human subjects research.
5. Monitors compliance.

C. IRB

1. Reviews proposals for any human subjects research conducted within the jurisdiction of the University.
2. Suspends or terminates approval when research is not conducted in accordance with requirements or is associated with unexpected serious harm to subjects.
3. Reviews investigators' financial management plans, if applicable.

D. Deans and Department Chairs

1. Oversee the review and conduct of human subjects research in their departments.
2. Report complaints or allegations of wrongdoing to the Organizational Official.

E. Sponsored Programs reviews contracts and funding agreement for compliance with the Human Research Protection Program.

V. Further Information

For additional information, contact IRB administration; irbadministration@ucdmc.ucdavis.edu; (916)703-9151; http://www.research.ucdavis.edu/c/cs/hrp.

VI. References and Related Policies

A. Code of Federal Regulations:

1. 21 CFR Part 56, Institutional Review Boards.
2. 45 CFR Part 46, Protection of Human Subjects

B. UC Office of the President:

1. Gender and Ethnicity Representation in Health Research.
2. Protection of Human Subjects in Research.

C. UCD Policy and Procedure Manual:

1. Section 220-05, Integrity in Research.
2. Section 230-02, Eligibility to Undertake Sponsored Research.
3. Section 230-05, Individual Conflicts of Interest Involving Research.
4. Section 230-07, Public Health Service Regulations on Objectivity in Research.
5. Section 240-30, Data Safety Monitoring Plans.