

UC Davis Policy and Procedure Manual

Chapter 240, Research Involving Human Subjects

Section 50, Principles and Policies

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Exhibit A, The Belmont Report

I. Statement of Principles

The University of California, Davis, subscribes to the concepts set forth in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Exhibit A) and accepts as basic principles the following:

A. Protection from risk

No human being will be exposed to unreasonable risk to health or well-being. All research activities will be conducted to avoid, or keep to the absolute minimum, risk to the health or well-being of the participants.

B. Criteria for involving human subjects

The risks to an individual must be minimized and reasonable in relation to anticipated benefits to him or her and by the importance of the knowledge to be gained; selection of subjects will be equitable; informed consent will be obtained and appropriately documented; privacy of subjects and confidentiality of data will be provided for; and additional safeguards to protect subjects will be required as needed.

C. Rights of subjects

The rights and welfare of all subjects involved will be adequately protected. These rights include:

1. The right to sufficient information about the research to allow an informed decision whether or not to participate.
2. The right to request and receive additional information during the course of the study.
3. The right to refuse to participate in or withdraw from the study at any time without penalty.
4. The right to protection and respect of personal privacy and to information regarding plans to disseminate confidential information.

D. Prior animal research

Whenever possible and relevant, animal research will precede research on human subjects.

E. Vulnerable populations

Additional and special precautions will be taken to protect the rights and welfare of subjects when research involves vulnerable populations such as the mentally or physically disabled, pregnant women, fetuses, children, prisoners, parolees, addicts, and others in conditions of dependency. The nature of such precaution will depend upon the type and extent of vulnerability

but shall be based upon respect for persons and concern for their welfare and be in accordance with Federal regulations.

F. University students as subjects

University students are vulnerable populations when a decision to participate as subjects is perceived to be required to prevent discrimination either in determination of course grades or in other activities of the academic department. If participation is part of the academic work of a student, it will not be a coercive or mandatory requirement, and reasonable academic alternatives will be provided to those not wishing to participate.

G. Foreign cultures

When research takes place in a foreign culture, the ethical principles and cultural traditions of that society will be respected, including use of the native language when providing information which may lead subjects to agree to participate in the study.

II. University Policy

The University Policy on the Protection of Human Subjects in Research, issued by the Office of the President on September 2, 1981, states:

"It is University policy that the regulations of the Department of Health and Human Services (HHS) ... are applicable to all research involving human subjects, as defined by these regulations, for which the University is responsible, regardless of the source of funding or whether the research is funded. In the case of conflict between regulations of the funding or regulatory agency and HHS the more restrictive regulations shall prevail."

III. UCD Policy

All research done under the auspices of UCD in which human subjects are involved must be reviewed and approved by the Human Subjects Review Committee (HSRC) appointed by the Chancellor according to the requirements set forth in Title 45, Part 46 and Title 21, Part 56 of the Code of Federal Regulations. Review and approval of use of human subjects in research according to Federal, State, and University policy and regulations applies to all studies in all locations, whether funded or unfunded, and whether conducted by faculty, students, or staff. It also applies to persons unaffiliated with the University who wish to investigate subjects who are under the protection of the University, such as students or patients. No such study may begin before it has been so approved, nor may it continue past its approved term.

IV. Sources of Policy

The UCD policy responds to legislation and regulation from several sources.

A. Department of Health and Human Services (HHS)

The principal source of policy and procedure regarding the protection of human subjects is the Department of Health and Human Services (formerly the Department of Health, Education, and Welfare). These regulations are set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46).

B. Food and Drug Administration (FDA)

Research involving investigational drugs, investigational devices, and all other articles subject to the Federal Food, Drug, and Cosmetic Act are governed by regulations set forth in 21 CFR 56.

C. Other agencies

Other Federal agencies, as well as the State of California, have published regulations and passed legislation for the protection of human subjects.

V. Definitions

The following definitions are used in this manual when discussing the use of human beings in research studies.

- A. Human subject--a living individual (including a human fetus) about whom an investigator conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private (personal or confidential) information [45 CFR 46.102(f)]. Obtaining identifiable information that is not publicly available regarding deceased individuals can also be considered research involving human subjects.
- B. Human subject of clinical investigation--(FDA) for purposes of FDA regulations, means an individual who is or becomes a participant in research either as a recipient of a test article or as a control. A subject may be:
1. A person in normal health, or
 2. A patient to whom the test article might offer a therapeutic benefit or provide diagnostic information or a better understanding of a disease or metabolic process, or
 3. A person hospitalized or otherwise under treatment for reasons unrelated to the study, considered in "normal health" for purposes of the study.
- C. Human Subjects Review Committee (HSRC)--functions as UCD's institutional review board (IRB). The Committee is charged with review and approval of research involving human subjects, unless such activities are specifically exempted from review by the Committee (refer to Sections 240-54 and 240-55). Research falling under the purview of the HSRC includes two major categories:
1. Biomedical and physiological studies such as administration of drugs, bone marrow aspirations, exercise testing, experimental surgery, all medical procedures, and any other physically invasive procedures or procedures capable of inducing an altered physiological state.
 2. Survey studies and noninvasive behavioral research such as telephone and in-person interviews, mailed questionnaires, psychology laboratory experiments, and anthropological and sociological field work.
- D. Investigator--a person who is responsible for and conducts research. Responsible investigators at UC include its faculty, students, staff, and administrators, and any other persons wishing to

conduct research using University facilities, personal records maintained by the University, or University faculty, staff, students, or patients as subjects of research.

Investigator, under FDA regulations, is an individual who actually conducts a clinical investigation, or in the event of an investigation conducted by a team of individuals, is the responsible leader of that team [21 CFR 56.102(h)].

- E. Investigational drug or device sponsor--(FDA) a person or establishment who is responsible for a clinical investigation. When University employees conduct an investigation, the University is considered to be the sponsor, and the employees are considered to be investigators.

If a University employee wishes to initiate a clinical investigation, the notice of sponsorship that is sent to the FDA must be filed by an administrative official of the University, indicating that the University accepts responsibility as sponsor. The responsible administrative office designated for UCD, including UCDCMC, is the School of Medicine Dean's Office.

- F. Medical experiment-- Under California law (AB 1752, California, 1978) a medical experiment is defined as any of the following:
1. The severance or penetration or damaging of tissues of a human subject, or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism in or upon a human subject, in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefiting such subject.
 2. The investigational use of a drug or device.
 3. The withholding of medical treatment from a human subject for any purpose other than maintenance or improvement of the health of such subject.
- G. Research--(AB 1592, California, 1977) a class of activities designed to develop or contribute to knowledge such as theories, principles, or relationships, or the accumulation of data on which they may be based, that can be corroborated by accepted scientific observation and inferences.

Research [45 CFR 46.102(e)] means a systematic investigation designed to develop or contribute to knowledge.

1. The use of an investigational drug or device automatically identifies an activity as research.
 2. The randomization of subjects into treatment groups, even if the treatments are standard accepted therapy, for the purpose of obtaining data constitutes research.
 3. Activities that meet this definition constitute research for purposes of this discussion whether or not they are supported by extramural or intramural sources.
 4. Some "demonstration," "evaluation," and "service" programs include research activities. If there is any element of research in an activity, it must undergo review for the protection of human subjects unless it qualifies for exclusion (see Section 740).
- H. Surgery as research--A surgical procedure is considered to involve research if any of the

following apply:

1. Surgical procedures are compared in a randomized manner.
 2. The procedure involves an investigational or a new implantable device.
 3. The investigator wishes to develop a procedure that has not previously been performed.
 4. The investigator wishes to study a procedure that is not accepted therapy or that might not be considered "best medical care."
 5. The development of a procedure is sponsored by an agency.
 6. The surgical procedure or activity is not routine in nature and is intended to yield publishable results.
- I. Test article--(FDA) any drug, biological product, medical device, food additive, color additive, cosmetic, electronic product, or any other article for human use subject to regulation under the Food, Drug, and Cosmetic Act or the Public Health Service Act (21 CFR 56.102).
 - J. Emergency use--(FDA) the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain HSRC approval (21 CFR 56.102).

VI. Questions

Questions concerning any aspect of research involving human subjects may be referred to the Human Subjects Assistant, Office of Research, (530)752-2075.