



Administrative Policy

Title: UCD Human Research Protection Program

Source: Office of the Vice Chancellor for Research

Prepared by: Interim Director for Regulatory Compliance

Approved by: Vice Chancellor for Research

Effective Date: August 2011, revised

Replaces: September 2008

Applies: All campuses

A. Introduction

To foster a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University of Colorado Denver and to ensure compliance with all University of Colorado Denver policies as well as all federal, state, and local laws and regulations.

B. Policy Statement

The University of Colorado Denver (UCD) has established a human research protection program (HRPP) which oversees the review and conduct of research involving human subjects under the auspices of UCD.

The HRPP is a multi-tiered program involving the Chancellor, the Vice Chancellor for Research, the Assistant Vice Chancellor for Research, the Office of Regulatory Compliance and its divisions, research committees, investigators and research support staff.

The HRPP includes mechanisms to:

- Establish a formal process to monitor, evaluate and continually improve the protection of human research participants.
- Dedicate resources sufficient to do so.
- Exercise oversight of research protection.
- Educate investigators and research staff about their ethical responsibility to protect research participants.
- When appropriate, intervene in research and respond directly to concerns of research participants.

The HRPP will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the Belmont Report). The actions of UCD will also conform to all other applicable federal, state, and local laws and regulations.

UCD Chancellor has designated Vice Chancellor for Research as the Institutional Official (IO) who has overall responsibility for the UCD HRPP. The duties of the Institutional Official are as follows:

1. Be responsible for compliance with institutional policies and all applicable regulations for the protection of human subjects.
2. Be the signatory authority for the Federal-wide Assurance to the Office of Human Research Protections.
3. Provide support to the human research protections program within the means of the institution.
4. Implement quality assurance and quality improvement programs as necessary for the protections of human subjects.
5. Suspend or terminate approval of research not being conducted in accordance UCD or regulatory requirements, policies, procedures, and guidance documents and research that has been associated with unexpected serious harm to participants.

In the performance of these duties, the IO has the authority to delegate such activities as may be necessary in order to fulfil these duties.

The Vice Chancellor for Research has designated the Assistant Vice Chancellor for Regulatory Compliance as the Compliance Officer for UCD and as such that position has the authority to investigate and manage matters of non-compliance or allegations of such as part of the UCD's Compliance Program. The Office of Regulatory Compliance is under the direction of the Assistant Vice Chancellor for Regulatory Compliance and is tasked with the development, implementation and management of UCD'S Compliance Program, including topics of conflict of interest, human subjects' research, research misconduct, research billing, export control, HIPAA privacy and data security. The offices supporting the Colorado Multiple Institutional Review Board (COMIRB), HIPAA Office and Conflict of Interest and Commitment Office (COIC), Research Quality Assurance and Education Program are divisions structured under the Office of Regulatory Compliance.

The Research Quality Assurance and Education Program not only conducts audits of individual research protocols but is also responsible for auditing the other compliance offices to ensure compliance with federal and state regulations and university policy.

The following committees serve in an advisory capacity on the functioning of the human subject protection program to the IO:

Clinical Translational Research Advisory Committee (CTRAC) responds to strategic needs for clinical and translational research for the University of Colorado Denver. It also serves as the Internal Advisory Committee for Colorado Clinical and Translational Sciences Institute (CCTSI). CTRAC has worked to improve interactions between patient- and community-based researchers and to strengthen compliance and support services. This committee meets monthly.

The Research Assistant Deans on the Downtown Campus meet at least quarterly, or more frequently as needed, to advise the Vice Chancellor for Research on policy, process and concerns relating to human subject research on the Downtown Campus.

Both the committees detailed above provide feedback to the Vice Chancellor for Research and the Assistant Vice Chancellor for Regulatory Compliance on the quality, and make recommendations to improve the HRPP. In addition, to cycle time data, the Vice Chancellor for Research and the Assistant Vice Chancellor for Regulatory Compliance use feedback obtained through audits, surveys or other pertinent data collection tools to evaluate the effectiveness of the HRPP. This information gathering is coordinated by the Evaluation Center and is used to develop a strategic plan to streamline process and improve efficiency.

The Evaluation Center is based in the School of Education and Human Development at the University of Colorado, Denver. The Evaluation Center serves as an institutional resource for program evaluation, providing comprehensive evaluations for the Colorado Clinical and Translational Sciences Institute (CCTSI), the College of Nursing, the NECTAR (Novel Educational Clinical Trainees and Researchers) program and a number of other pipeline initiatives. All of these programs are designed to build institutional capacity for responsive research, training and practice. The aim of the Evaluation Center is to measure (in terms of outcomes and longer-term impacts related to the Human Research Protections Program) by leveraging these methods and data sources outlined in the comprehensive UCD/CTSA Evaluation Matrix for HRPP. Associated reports are provided to the senior leadership of the CCTSI (program directors and steering committee members) on a regular (quarterly) basis.

To conduct its responsibility effectively, UCD maintains Institutional Review Boards (IRB) to review research protocols involving human subjects. The IRB is an autonomous administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of UCD. Research that has been reviewed and approved by IRBs may be subject to review and disapproval by officials of the institution. However, those officials may NOT approve research if it has not been approved by one of the IRBs panels.

The IRB has the following authority:

1. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of UCD;
2. To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants;
3. To observe, or have a third party observe, the consent process; and
4. To observe, or have a third party observe, the conduct of the research.

All IRB approved research studies are subject to ongoing review, which must be conducted at least once annually by the IRB. If approval by the IRB lapses, all research activity must stop unless the IRB finds that there is an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating in the research interventions or interactions.

The IRB has jurisdiction over all human subject research conducted under the auspices of UCD. Research considered under the auspices of UCD include all research involving human subjects that is conducted completely or partially in UCD facilities, conducted in approved off-site locations, facilities, and/or conducted by UCD employees or staff.

Investigators receiving support from other Federal agencies, such as the National Institutes of Health (NIH), must meet requirements for the protection of human subjects of the funding source in addition to those of the institution. Where FDA-regulated test articles are used, the FDA regulations apply regardless of funding source (21 CFR Parts 11, 50, 54, 56, 312, 314, 600, 812, and 814). For VA research, all regulations pertaining to the participation of veterans as subjects including requirements for indemnification in case of research-related injury pertain to non-veteran subjects enrolled in VA-approved research.

All institutional and non-institutional performance sites for UCD, domestic or foreign, will be obligated by this policy to conform to ethical principles which are at least equivalent to those of UCD.

The IO and the IRBs shall adopt operating procedures to implement this policy that will serve as the governing procedures for the conduct and review of all human research conducted under the auspices of the UCD.

C. Definitions

Human Subject. A human subject as defined by the Common Rule means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46.102(f)).

- Intervention as defined by the Common Rule means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. [45 CFR 46.102(f)]
- Interaction as defined by the Common Rule means communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)]
- Private information as defined by the Common Rule means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). [45 CFR 46.102(f)]
- Identifiable information as defined by the Common rule means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

For research covered by Food and Drug Administration (FDA) regulations (21 CFR 50 and 56), human subject means an individual who is or becomes a participant in a clinical investigation (as defined below), either as a recipient of the test article or as a control. A subject may be in normal health or may have a medical condition or disease. In research involving devices, a human subject means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control (21 CFR 812).

Research. Research as defined by the Common Rule means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge (45 CFR 46.102(d)).

Research as defined by FDA regulations means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

- Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act” means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]
- Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act” means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]
- Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]

IRB. An IRB is a board established in accordance with and for the purposes expressed in the Common Rule (45 CFR 46.102(g).) Within UCD, the IRB is known as the Colorado Multiple Institutional Review Board for all biomedical research conducted at UCD and social and behavioral research conducted on the Anschutz Medical Campus. The Human Subject Review Committee is the IRB for all social and behavioral research conducted on the Downtown Campus.

Institutional Official (IO). The IO is currently the Vice Chancellor for Research. The IO is the UCD official responsible for ensuring that the HRPP at the facility has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official for all Assurances, and assumes the obligations of the institution’s Assurance. The IO is the point of contact for correspondence addressing human subjects research with OHRP, FDA, and the Affiliates.

Human Research Protection Program (HRPP). The HRPP is a multi-tiered program which oversees the review and conduct of research involving human subjects under the auspices of UCD and is closely interlined with the HRPP of the affiliate hospitals.