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Scope

Throughout this document “organization” refers to the University of Colorado Denver.

Policy

The University of Colorado Denver (UCD) has established a Human Research Protection Program (HRPP) that is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research and oversees the review and conduct of research involving human subjects under the auspices of UCD. The Human Research Protection Program shall ensure compliance with all University of Colorado Denver policies as well as all federal, state, and local laws and regulations.

The HRPP is a multi-tiered program involving the Chancellor, the Vice Chancellor for Research, the Associate 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 the Vice Chancellor for Research as the Institutional Official (IO) who has overall responsibility for the UCD HRPP.

The Human Research Protection Program shall adopt operating procedures, The UCD HRPP Policies and Procedures, which will govern the conduct and review of all human research conducted under the auspices of the UCD.

Purpose

This organization is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this plan is to describe the organization’s plan to
comply with ethical and legal requirements for the conduct and oversight of Human Research.

This organization’s Human Research Protection Program is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The Human Research Protection Program requires that all individuals in this organization, along with key individuals and committees, fulfill their roles and responsibilities described in this plan.

**Definitions**

**Agent**

An individual who is an employee is considered an “agent” of this organization for purposes of engagement in Human Research when that individual is on-duty in any capacity as an employee of this organization.

An individual who is not an employee is considered an “agent” of this organization for purposes of “engagement in Human Research” when that individual has been specifically authorized to conduct Human Research on behalf of this organization and has signed contractual and confidentiality agreements with legal review.

**Clinical Trial**

A biomedical or behavioral research study of human subjects designed to answer specific questions about therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new therapeutic interventions are safe, efficacious, and effective.

**DEA Schedule 1 drugs**

Drugs, substances, and certain chemicals used to make drugs are classified into five (5) distinct categories or schedules depending upon the drug’s acceptable medical use and the drug’s abuse or dependency potential.

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence. Some examples of Schedule I drugs are:

- heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote

**Engaged in Human Research**

This organization is engaged in Human Research when its employees or agents are interacting or intervening with Human Subjects for the purpose of conducting
research. This organization follows OHRP guidance on “Engagement of Institutions in Research” to apply this definition.

**Human Research:**
Any activity that either:
- Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
- Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

**Human Subject as Defined by DHHS**
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) information that is both Private Information and Identifiable Information. For the purpose of this definition:
- **Intervention** means 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.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** 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).
- **Identifiable Information** 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 conducted or funded by the Department of Defense (DOD):**
  When there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction the data are considered to be about the living individual.
- **For research conducted within the Bureau of Prisons:** Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

**Human Subject as Defined by FDA**
An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.
Institutional Review Board (IRB)
An IRB is a board established in accordance with and for the purposes expressed in the Common Rule.

Institutional Official (IO)
The IO is the University 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 subject research. The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of its Federal-wide Assurance.

Investigator
The person responsible for the conduct of the Human Research at one or more research sites. If the Human Research is conducted by a team of individuals at a research site, the investigator is the responsible leader of the team and may be called the principal investigator.

Research as Defined by DHHS
A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research as Defined by FDA
Any experiment that involves a test article and one or more human subjects and that meets any one of the following:

- 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, meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- 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, meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity 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.

Test Article
A test article is a drug, device, or other article including a biological product used in clinical investigations involving human subjects or their specimens.
Mission

The mission of this organization’s Human Research Protection Program Plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by this organization.

Ethical Requirements

In the oversight of all Human Research, this organization (including its investigators, research staff, students involved with the conduct of Human Research, IRB members and Chairs, IRB staff, the Institutional official, employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report,” found in the “references” section of our website.

- Respect for Persons
- Beneficence
- Justice

Legal Requirements

This organization commits to apply its ethical standards to all Human Research regardless of funding.

When this organization is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, the organization commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When this organization is engaged in FDA Human Research, this organization commits to apply the FDA-regulations relevant to the protection of Human Subjects.

Any questions about whether an activity meets the regulatory definitions of Human Research can be referred to the CRSC or IRB which will provide an opinion. Only COMIRB can make a formal determination, if needed.

There is also a Quality Improvement / Program Evaluation / Research tool available on the COMIRB website to document the research teams thought process and assessment of whether the project meets the regulatory definition of Human Research.

Other Requirements

When reviewing research that is considered community based research, the IRB considers the Community-Based Research Principles at:

All policies and procedures that are applied to Human Research conducted domestically are applied to Human Research conducted in other countries.
For clinical trials, this organization commits to apply the “International Council on Harmonization – Good Clinical Practice E6” when obligated to in clinical trials agreements or other funding agreements to the extent permitted under FDA regulations.

This organization prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)

When Human Research is conducted or funded by the Department of Justice (DOJ), this organization commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the organization commits to comply with 28 CFR §512.

When Human Research is conducted or funded by the Department of Defense (DOD), this organization commits to apply DOD Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D\(^1\). When Human Research is conducted or funded by the Department of the Navy, the organization commits to apply SECNAVINST 39000.39D.

When Human Research is conducted or funded by the Department of Education (ED), this organization commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.

When Human Research is conducted or funded by the Department of Energy (DOE), this organization commits to applying DOE O 443.1A.

When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this organization commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

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\(^1\) Quick applicability table for DHHS Subparts:

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Sponsored Human Research
For both sponsored and non-sponsored Human Research, this organization abides by its ethical principles, regulatory requirements, and its policies and procedures.

Scope of Human Research Protection Program
The categories of Human Research overseen include:

- All forms of human research
- Department of Defense (DOD) research
- Department of Justice (DOJ) research
- Department of Education (ED) research
- Department of Energy (DOE) research
- Environmental Protection Agency (EPA) research
- Other Federally funded research
- Research involving fetuses.
- Research involving in vitro fertilization.
- International research
- FDA-regulated research.
- Research involving drugs that require an IND.
- Research involving devices that require an abbreviated IDE.
- Research involving devices that require an IDE issued by FDA.
- Investigator held abbreviated IDE.
- Investigator held IND or IDE.
- Research involving pregnant women as subjects.
- Research involving non-viable neonates.
- Research involving neonates of uncertain viability.
- Research that plans to or is likely to involve prisoners as subjects.
- Research involving children as subjects.
- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director.
- Research involving a waiver of consent for planned emergency research.
- Emergency use of a test article in a life threatening situation.
- Activities involving humanitarian use devices.
- Research using the short form for consent documentation.

Human Research Protection Program Components

Institutional Official
UCD Chancellor has designated the Associate Vice Chancellor for Regulatory Compliance as the Institutional Official (IO) who has overall responsibility for the UCD HRPP.
The Institutional Official has the authority to take the following actions or delegate these authorities to a designee:

- Create the HRPP budget.
- Allocate resources within the HRPP budget.
- Appoint and remove IRB members and IRB Chairs.
- Hire and terminate research review staff.
- Determine the IRBs that the organization will rely upon.
- Approve and rescind IRB authorization agreements.
- Place limitations or conditions on an investigator’s or research staff’s privilege to conduct Human Research.
- Create policies and procedures related to the HRPP.
- Suspend or terminate IRB approval of research.
- Disapprove research approved by the IRB.

The Institutional Official has the responsibility to take the following actions or delegate these responsibilities to a designee:

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
- Periodically review this Plan to assess whether it is providing the desired results and recommend revisions.
- Establish policies and procedures designed to ensure that Human Research will be conducted in accordance with ethical and legal requirements.
- Institute educational and training programs for all individuals involved with the Human Research Protection Program.
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the organization cannot approve research that has not been approved by an IRB designated by the organization.
- Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas and, where necessary, removal of individuals from involvement in the Human Research Protection Program.
- Ensure that the Human Research Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, such that reviews are accomplished in a thorough and timely manner.
- Review and sign federal assurances (FWA) and addenda.
The Chancellor has also designated the Associate Vice Chancellor for Regulatory Compliance to have day to day responsibility for the UCD HRPP as well as being the Research 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 Associate Vice Chancellor for Regulatory Compliance and is tasked with the development, implementation and management of UCD’s Compliance Program, including:

- Regulatory Compliance committees
- Conflict of interest,
- Human subjects’ research,
- Research misconduct,
- Research billing,
- Export control,
- Regulatory compliance,
- HIPAA privacy and data security.

**Affiliated Hospitals and Research Centers**

UCD and the affiliated hospital and research centers listed herein have established the responsibilities and authority of the components of the HRPP under Memorandums of Understanding between UCD-Anschutz Medical Campus and the individual affiliated hospital or research centers.

Each affiliated hospital or research center manages its administrative processes for reviewing and approving research protocols that involve human subjects, including the management of research funding and requirements set forth by research sponsors. In the course of this process, the affiliated hospitals and research centers have agreed to adhere to the standards set forth in the UCD HRPP. As needed, each affiliated hospital or research center conduct scientific reviews for the purpose of conducting ethical research.

The Associate Vice Chancellor for Research meets at least annually with the key parties from each affiliate and other appropriate interested parties to maintain an effective integration of the HRPP for UCD with the HRPP for each affiliated hospital.

The Office of Regulatory Compliance addresses issues of non-compliance with the associated compliance or regulatory office of the affiliated hospital or research center as appropriate if concerns or non-adherence to UCD’s HRPP arise. On a regular basis, the Office of Regulatory Compliance and the affiliated hospitals and research centers meet to discuss programmatic concerns as well as prospective ways to ensure the safety and well-being of human research participants.
Affiliated hospitals and research centers are as follows: the University of Colorado Hospital (UCH), Children’s Hospital Colorado (CHCO), Denver Health Medical Center (DHMC), and the Denver Veteran’s Affairs Medical Center (DVAMC).

UCD holds one Federal Wide Assurances (FWA) from the Office of Human Research Protections (OHRP) in the Department of Health and Human Services (FWA# 00005070).

All members of the organization

All individuals within the organization have the responsibility to:

- Understand the definition of Human Research.
- Consult the IRB when there is uncertainty about whether an activity is Human Research.
- Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the Institutional Official.
- Report allegations or finding of noncompliance with the requirements of the Human Research Protection Program to the IRB.

IRBs

The list of IRBs designated by the Institutional Official as the IRBs relied upon by the Human Research Protection Program and the scope of review of these IRBs is available in the Office of Regulatory Compliance. The IRBs at the University of Colorado Denver are collectively known as the Colorado Multiple Institutional Review Board or COMIRB.

This organization may rely upon the IRB of another organization provided one of the following is true:

- The IRB is the IRB of an AAHRPP accredited organization.
- This organization’s investigator is a collaborator on Human Research that is primarily conducted at another organization and the investigator’s role does not include interaction or intervention with subjects.
- The organization is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)
- The university has a long standing relationship with the IRB, for example National Jewish Health.
The IRBs relied upon by this organization have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the organization. All Human Research must be approved by an IRB designated by the Institutional Official. Officials of this organization may not approve Human Research that has not been approved by the IRB.
- Suspend or terminate approval of Human Research not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the Human Research.
- Determine whether an activity is Human Research.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.

COMIRB members and COMIRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to COMIRB members and staff.

**Investigators and Research Staff**

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements, policies and procedures.
- Comply with all determinations and additional requirements of the IRB, the IRB Chair, and the Institutional Official.

**Legal Counsel**

Legal Counsel has the responsibility to:

- Provide advice upon request to the Institutional Official, IRB, and other individuals involved with the Human Research Protection Program.
- Determine whether someone is acting as an agent of the organization.
- Determine who meets the definition of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.

**Deans/Department Chairs**

Deans and Department Chairs have the responsibility to:
• Oversee the review and conduct of Human Research in their department or school.
• Forward complaints and allegations regarding the Human Research Protection Program to the Institutional Official.
• Ensure that each Human Research project conducted in their department, division or school has adequate resources.

Clinical Research Administration Office
This office is the central office that has overall responsibility for all activity associated with human subject research. It includes:

• The Clinical Research Support Center
• Clinical Trials Contracting
• Pre-approval for UCD and the Affiliate hospitals
• Clinical Trials Management System implementation
• External IRB management

Clinical Research Support Center (CRSC)
The Clinical Research Support Center provides education, expertise, and guidance to clinical research professionals at UCD and its affiliates. The CRSC provides assistance with regulatory submissions to the COMIRB, FDA and others upon request. The CRSC strives to promote efficiency, standardization, compliance and responsible clinical research conduct through education, quality assurance visits, and serve as a thoughtfu leader in the field of clinical research.

Grants and Contracts Office
The Grants and Contracts Office has the responsibility to review federal, state or foundation sponsor contracts and funding agreements for compliance with Human Research Protection Program Policies and procedures.

Scientific Advisory Review Committee (SARC)
SARC is a committee of experienced investigators, and biostatisticians, with feasibility input from CTRC core staff. The purpose of SARC is to evaluate the scientific merit of research protocols for the campus. All investigator-initiated protocols that have not received a full peer review are reviewed by SARC. NIH-funded protocols and other protocols that have received prior peer review undergo an expedited review process. Major scientific changes to a protocol post peer review, will also be reviewed by SARC.

Conflict of Interest and Committee Office and Committee
The COIC Committee exists to protect the integrity of investigators and UCD and to maintain the public trust in UCD as a state institution that serves the citizens of the
State of Colorado. Because significant financial and other conflicts of interest and commitments can harm the reputation of UCD, as well as adversely affect its ability to fulfill its missions in education, patient care and research, these conflicts should be subject to the oversight and recommendations of a duly-constituted and broadly representative committee. UCD’s COIC Committee serves these functions. The Committee identifies, manages and minimizes actual and potential conflicts of interest and commitment where they exist. The Committee carries out this charge in a manner that is intended to foster, not hinder, research relationships. The COIC Office serves as a resource to the UCD faculty and staff, and provides training and administrative support to the COIC Committee.

Institutional Conflict of Interest Management

UCD Institutional Conflict of Interest is governed by the University of Colorado “Conflicts of Interest and Commitment” policy. It is operationalized by the COIC Office and Committee in accordance with their SOP.

Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) reviews and registers research involving the deliberate transfer of DNA (or RNA derived from recombinant DNA) into one or more human participants. This use is subject to continuing review. The COMIRB will not issue final approval for protocols requiring approval from the IBC without documentation that the IBC has reviewed and approved the protocol. Unanticipated problems that occur in these protocols require reporting to the IBC and the COMIRB simultaneously. The Director of the IRB serves as a non-voting member of the IBC committee to ensure good communication between the offices.

Institutional Dual Use Research of Concern Oversight

The requirements for the Institutional oversight of Dual Use Research of Concern (DURC) are facilitated by the Export Control Officer in collaboration with the Institutional Biosafety Officer. The Institutional Review Entity draws on the expertise of the IBC.

Committee for Ionizing Radiation

Committee for Ionizing Radiation (CIR) oversees research involving the administration of therapeutic radiation doses using sealed sources that the participant would not otherwise receive as part of regular medical care. While investigators are encouraged to submit these protocols to the COMIRB Office and the CIR simultaneously, the COMIRB will not approve submissions requiring approval from the CIR without documentation of CIR review and approval in the protocol file.
The Radioactive Drug Research Committee

The Radioactive Drug Research Committee (RDRC) is authorized by the FDA to review and approve research which involves the use of certain “non-approved” radioactive drugs studies under the following conditions: when investigating human physiology, pathophysiology or biochemistry, metabolism, localization, kinetics, and distribution. Investigators are required to submit these protocols to the COMIRB Office and the RDRC simultaneously. The COMIRB will not approve submissions requiring approval from RDRC without documentation of RDRC review and confirmation that the protocol is approvable in the protocol file. The Quality Assurance and Education team from the CRSC will conduct site initiation visits for all new RDRC protocols and perform audits at least annually to confirm compliance with all applicable regulations and requirements. Quarterly reports will be provided to the RDRC committee via OnCore or the Principal Investigator for the study.

Pharmacy

Research involving administration of an FDA test article that are non-formulary or for which use is restricted at an affiliated hospital or research center requires review by the affiliated hospital or research center. Investigational products that will be managed and dispensed by the affiliate pharmacy do not need to be reviewed by the Investigational Product Review Committee.

Marijuana Research

The University of Colorado by virtue of being located in Colorado should be involved in the ongoing study of marijuana and its legalization. However, DEA still identifies marijuana as a Schedule 1 drug (substances with no currently accepted medical use).

The following are the areas of human subject research involving marijuana that are currently allowed and approved:

- Human Subject/Clinical Trials-As with any schedule 1 drug, there already exists strict protocols, procedures, and approvals that must be obtained from the Food and Drug Administration (“FDA”) before use in humans.
- Observational Studies-The University of Colorado already conducts observational studies for users of many types of substances. Again, any observational study that involves interviewing users must be reviewed and approved by a campus IRB.

The following are areas of research involving marijuana that cannot be undertaken without prospective approval from legal counsel:

- Research that involves bringing marijuana onto campus that has not been properly obtained from the FDA. This includes testing marijuana for marijuana growers to determine whether marijuana is contaminated or to determine its level of THC.
• Marijuana research that involves providing marijuana to human subjects, subsidizing the purchase of marijuana, or studying the first-person effect of marijuana on human subjects that do not have an IND or are approved by the FDA.

Export Control

The Export Control Officer is responsible for ensuring that UCD complies with all export control requirements. It is a centralized resource to provide training and oversight of the program and works closely with key offices to ensure that the majority of research at UCD is within the fundamental research exemption. When needed the Export Control Officer develops the technology management plans and provides monitoring support to ensure compliance with the plan.

International Research Advisory Committee

All human subject research protocols that involve the PI or members of the research team traveling outside the USA to recruit, consent, conduct research activities and/or collect data are required to be pre-reviewed by the International Research Advisory Committee (IRAC) prior to the normal protocol review by COMIRB as detailed in this document for initial full board or expedited protocols. Additionally, any research which is funded by the PI (or PI’s grant), or research occurring in another country under the direction of the PI (or the PI’s protocol), must be pre-reviewed by the IRAC. Whenever possible, IRB or ethics review and approval will be required from the local country where the research will occur.

Human Fetal Tissue and Scientific Ethics Committee

The University has produced an Administrative Policy, Conducting Human Fetal Tissue Research, not to prohibit the use of these tissues, but to make clear that all such research conducted at this institution must be reviewed and approved in accordance with any applicable federal or state laws, and regulations regarding such activity. Researchers at the University of Colorado Denver| Anschutz Medical Campus are required to follow the institution’s policy and procedures as outlined in the documents below.

The policies and procedures outlined in the documents apply to research using human fetal tissue, whether it be identifiable, coded, de-identified or anonymous. These also
include human embryonic stem cells that are not listed in the NIH embryonic stem cell registry.

This policy does not apply to the use or collection of placental or umbilical materials, amniotic fluid, nor human embryonic stem cells listed in the NIH embryonic stem cell registry. The procedures addressed here do not apply to the clinical care of women and their fetus or the procurement of Human Fetal Tissue intended for clinical purposes only. Use of human fetal tissue must either be reviewed by COMIRB or the Scientific Ethics Committee before it can be collected, transferred or used at UCD.

**Investigational Product Review Committee**

The Investigational Product Review Committee (IPRC) provides overall review and guidance for the investigator initiated, locally developed and compounded investigational products. It also provides review of any research protocol that intends to store, dispense or manage investigational product outside of a hospital pharmacy. The approval and recommendations of the IPRC must be in place before a study can enroll subjects.

**Communication and Education**

**Education and Training**

IRB members, investigators, and research staff must complete the on-line Collaborative Institutional Training Initiative (CITI) human subject on-line training program.

The required CITI courses are as follows:

- Either the basic or refresher medical course; or the basic or refresher social and behavioral course. Non-UCD employees who cannot access CITI must submit proof of comparable training. This training is valid for a three-year period.
- For the Principal Investigator conducting FDA-regulated research (e.g., investigation of a novel therapeutic drug, device, or biologic), the Good Clinical Practice for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) course must also be taken. This training is valid for a three-year period.
- CITI Health Information Privacy and Security (HIPS) for either: Clinicians, Clinical Investigators, Students and Instructors, Fundraisers, Marketers, depending on the individual’s role. This training is valid for a three-year period.
The institutions, recognizing the need for support, problem solving, and quality improvement, created the Clinical Research Support Center (CRSC). The CRSC provides support to researchers and their teams in terms of IRB and FDA submissions, study management, education, training and outreach. The Clinical Research Support Center provides additional ongoing and comprehensive training and educational opportunities for research staff.

In order to meet the requirements of the NIH for trainees, fellows, participants and scholars receiving support through any NIH training, career development award, research education grants and dissertation, the University of Colorado Denver has developed its Responsible Conduct of Research (RCR) training. The training is offered frequently enough to allow participants to meet the NIH requirements of this training at least once during their careers and no less than once every 4 years.

**Clinical Research Education Program**

The Clinical Research Education Program is a key component of the Clinical Research Support Center and in collaboration with the Colorado Clinical and Translational Science Institute provides face to face training for researchers and clinical coordinators. The courses span the range of basic, intermediate and advanced classes and the curriculum is refined based on the results of periodic monitoring visits with research teams.

**Research Integrity**

The Associate Vice Chancellor for Regulatory Compliance is the Research Integrity Officer (RIO) for UCD. The RIO oversees any allegations of research misconduct, provides resources to facilitate a culture of compliance and is responsible for the Responsible Conduct of Research training on both campuses.

**Support for Sponsor Investigators**

When a UCD investigator plans to hold an IND or IDE for a study, the CRSC provides support, guidance and assistance with the submission to the FDA, development of materials and documents for study management and can provide site initiation visits for investigators. Once the IND or IDE has been approved by the FDA, the CRSC will provide ongoing support with submissions of amendments, and annual reports. The CRSC also provide reminders to sponsor investigators when their annual reports are due to the FDA. The Clinical Research Support Center will perform a QA visit with each UCD sponsor-investigator at least once each year. The purpose of these visits is to confirm compliance with the regulations and IRB approved protocol and provide guidance and suggestions for best practices, and practice improvement as necessary.
Clinical Trials Registration

University complies with FDAAA, NIH, CMS, and ICMJE clinical trial registration and reporting requirements.

The Principal Investigator of an Investigator-initiated, interventional clinical trial that meets FDAAA, NIH, CMS, ClinicalTrials.gov registration and reporting requirements is responsible for posting the requisite information on the University’s organizational account on ClinicalTrials.gov.

The Principal Investigator of all interventional clinical studies that would like to be considered for publication within an ICMJE journal must register the clinical trials in a public trials registry.

Registration and results reporting must occur within the timeframe set by FDAAA, NIH, CMS and/or ICMJE, as applicable with whichever timeframe is earliest.

Registration and results reporting of clinical trials is required when the study is:

1. FDA regulated clinical trials (other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation).

2. National Institutes of Health funded Clinical Trials (fully or partially funded)


University researchers are responsible for ensuring that clinical trials are registered in ClinicalTrials.gov in a timely manner; reviewing the content of the clinical trial information posted on ClinicalTrials.gov; reviewing the clinical trial record for any inconsistencies and/or errors and reviewing the clinical trial record as required to verify that updating is taking place as required.

It is the responsibility of the Principal Investigator to register the trial in accordance with the following timelines:

FDAAA requires that the RP (or designee) for an ACT must submit required clinical trial information through the PRS no later than 21 days after enrollment of the first participant. → https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa

The NIH requires registration and results reporting for all NIH supported clinical trials, regardless of study phase, type of intervention, or whether or not they are subject to FDAAA. These studies should be registered no later than 21 days after


ICMJE requires trial registry at or before first patient enrollment as a condition for publication → http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/

Principal Investigator Responsibilities for Updating ClinicalTrial.gov Records

Registration information must be updated no less than once every 6 months.

If recruitment status for the study changes (e.g., recruitment suspended), the registration must be updated within 30 days

If the trial is complete (whether concluded or terminated prior to conclusion), registration must be updated within 30 days

Results Reporting Aggregate results reporting, including reporting of adverse events, are required if the trial meets one of the following requirements:

The trial meets the definition of an Applicable Clinical Trial specified in FDAAA. Reporting aggregate results and adverse events on ClinicalTrials.gov must occur within 12 months of the Primary (endpoint) Completion Date; or Last updated

• The trial is NIH-supported, in whole or in part, are required for results submission no later than one year after the trial’s Primary Completion Date; or

• A study registered on the University’s organizational account and is identified as a probable ACT/non-probable ACT based on its study information on ClinicalTrials.gov

The Clinical Research Support Center (CRSC) provides guidance, administrative support and assistance in all aspects of clinical trials registration. COMIRB makes the determination that a study is an applicable clinical trial under the regulations. Researchers are advised at the time of IRB review of the requirements for posting on the National Library of Medicine site, ClinicalTrials.gov. When notified, PIs contact the CRSC for help in setting up an account, setting up a record, and subsequent responses to reviews and other posting requirements. Biostatistical support is available to assist researchers enter results.

**Communication to constituents**

Communication to the Principal Investigators and the broader research team is primarily via:
• CRSC monthly newsletter
• VC for Research’s bi-monthly newsletter
• Broader notices also use faculty announcements

**Use of External IRBs**

Since 2005, UCD has had a relationship with Western IRB (WIRB) to facilitate a centralized IRB approach to industry sponsored research.

NCI CIRB is used by the UCD Cancer Center in accordance with NCI policies and procedures. DHHA also utilizes NCI CIRB via a relationship with Colorado Community IRB.

Denver VA is also piloting the use of NCI CIRB for appropriate oncology protocols.

UCD in collaboration with the affiliate hospitals has also entered into a number of memorandum of understanding and IRB Reliance Agreements to facilitate a centralized approach to IRB review for federally funded research.

Investigators may also request via the Portal application to cede to another IRB. This mechanism will be considered for more than minimal risk research only if the alternative IRB is accredited or is a local partner with whom UCD has a long standing relationship such as National Jewish and Boulder.

Management and oversight of the external IRB process is by the external IRB coordinators. Their role is to collect the study documents for UCD reference, manage the relationship with the external IRB and ensure coordination of the institutional responsibilities that frequently are maintained locally such as training requirements, HIPAA privacy board oversight, conflict of interest management and other regulatory committee approvals specific to the research anticipated.

**Process Review and Monitoring**

**Portal:**
Since 2014, UCD, CCTSI, CHCO and UCHealth have collaborated to improve efficiency and avoid duplication of documentation by having a single portal for requests for approval at each facility. This review may include a feasibility and budget review.

**Clinical Trial Management System:**
In 2013, UCD purchased the license to implement OnCore as its clinical trial management system. To provide a backbone infrastructure support system for clinical research conducted by UCD faculty.
The initial pilot program was launched in August 2014 involving renal, orthopedics and otolaryngology. The Cancer Center completed its data conversion August 2015 and since April 2017 the system has been expanded to include all human subject research conducted on the Anschutz Medical Campus.

Integrations with InfoEd and Epic currently exist and will continue to expand to provide an integrated system for managing and reporting on the research portfolio.

**Oversight of the Human Research Protection Program**

**OVCR meeting** – the UCD VC for Research and Institutional Official has a monthly meeting of the HRPP directors;

**C-TRAC** – established by the Dean of the School of Medicine and the VC for Research as a mechanism for key research team leaders to provide input and advice to improve the efficiency and effectiveness of the UCD HRPP and the HRPP programs at the affiliate hospitals. It generally meets monthly.

UCD and UCH Health Research Advisory Forum is an informational and advisory forum for all constituents of the HRPP and includes key constituents of the HRPP programs at the two institutions.

External Advisory Committee CCTSI – this committee includes external key personnel from peer institutions who meet annually to review the work of the CCTSI. The CCTSI is a key component of the infrastructure support for the UCD HRPP.

**Evaluation of the Human Research Protection Program**

In 2012, a quality improvement plan was developed for the UCD HRPP. The metrics outlined in the quality improvement plan are reviewed annually by the AVC for Regulatory Compliance and provided to the IO and other oversight committees. Every three years a written evaluation of the HRPP is provided to the Institutional Official as part of the strategic planning for the HRPP.

External Advisory Committee CCTSI – evaluates key components of the UCD HRPP annually in the form of a written report to the IO and Dean of the School of Medicine.

The Evaluation Core within the School of Education conducts a Needs Assessment with research faculty every 2 to 3 years to obtain feedback from the research teams on research resources and infrastructure. These data are reviewed and used as a guide to develop additional education, training or other infrastructure needs.
Community partnerships with UCD
Community Engagement (CE) Core

The Community Engagement (CE) Core through the Partnership of Academicians and Community for Translation (PACT) works together to facilitate community based participatory research (CBPR); educate and connect investigators and communities; develop programs to improve relationships and build trust between academics and communities and build capacity in community academic partnerships, and provide funds for community engagement in research.

The mission of this group is to transform the way communities and researchers work together to design and conduct research by building bridges between health research, clinical practice, and community health initiatives to improve the health of the people of Colorado and the Rocky Mountain Region.

The Community Engagement core is supported by the Colorado Clinical and Translation Science Institute and funded by the NIH.

Community Research Liaisons reside in their own communities and have received training in CBPR and translation research. They establish working partnerships between academic researchers and individuals within a community. They have been described as facilitators, ambassadors, confidants, and educators. The relationships facilitated by the Community Research Liaisons can create community based participatory research projects that better inform research and identify interventions which ultimately improve the health of the community.

The PACT Council provides oversight and direction for all community engagement activities. Dedicated committees provide oversight and direction:

- Executive Committee
- Business Administration Committee
- Community Consults and Ethics Committee
- Education and Training Committee
- Pilot Grant Committee

Pipeline Programs

There are numerous pipeline programs to connect local schools with academic science. These programs include:

- Undergraduate pre-health Program (UPP)
- MCAT study academy
- CREATE – supports pre-health education in rural and urban underserved communities
• Aurora Lights – collaborates with Aurora public schools
• SURF - Summer Undergraduate Research Fellowship Program

**Mini-Med School**

The mini-med school has been an important way to engage the local community since its inception in 1989. The original Mini Med class is now available on-line and there is a Mini-Med II – The Clinical Years which is available to the public as a series of lectures.

**Consultation services**

Ethics Consultation Services – a resource provided as a collaboration between the AMC Center for Bioethics and the CCTSI. It is available to all biomedical and behavioral researchers at the University of Colorado Denver, as well as its clinical affiliates, who seek advice about ethically complex aspects of their research.

Community Engagement Consult - brings together experts in community engagement to help investigators address the community relevance of their research activities as well as to help communities ask and answer questions about their health.

**Evaluation of community outreach**

External Advisory Committee CCTSI – evaluates key components of the UCD HRPP including community outreach annually in the form of a written report to the IO and Dean of the School of Medicine.

The Evaluation Core of the School of Education has developed a survey to evaluate the effectiveness of the community liaison program. A report will be provided annually to CCTSI leadership and the IO with regard to this program.

Anschutz Medical Campus leadership established the Community-Campus Partnership (CCP) in 2013 to evaluate the needs of the local community so as to develop goals and activities under the mission of “Neighbors working together for healthy, vibrant communities. This partnership provides an annual report to the Chancellor and IO.

**Reporting and Management of Concerns**

Questions, concerns, complaints, allegations of undue influence, allegations or findings of serious or continuing non-compliance, or input regarding the Human Research
Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the Institutional Official, Office of Regulatory Compliance, IRB, Legal Counsel, Deans, or Department Chairs.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The AVC for Regulatory Compliance has the responsibility to investigate all other reports and take corrective actions as needed.

CU EthicsLine allows individuals to anonymously report concerns involving a possible violation of law, regulation, policy, or report issues that cannot be handled or reported through normal channels. The employee may complete a report via:

- A toll-free phone number (800) 677-5590, or

This reporting service is provided by EthicsPoint, an independent company. The service provides a communication option available seven days a week, 24-hours a day. The University of Colorado Internal Audit Department or other designated contact receives notifications of reports filed and will conduct the investigation or assign the report to another individual qualified to investigate the concern. The individual who reported the concern may access the report periodically through EthicsPoint using an assigned report number and a password to determine the status, report additional information regarding the issue, or to answer questions the investigator has posted.

At UCD, all reports are managed through the Office of Regulatory Compliance. In this role, the IO or designee reviews and ensures that any matter related to the human subject protections is reviewed in accordance with UCD’s HRPP plan and/or policies and procedures.

Employees who report possible compliance issues in good faith are not subject to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the IO or designee.

**Reports by Research Participants**

Participants in research will be provided contact information for questions, concerns or reporting complaints to the IRB Offices within the informed consent document. Additionally, the websites for IRBs provide contact information, as well as a way to anonymously report to the respective IRBs any questions, concerns or complaints that they may have. Finally, participants in research can contact the IO through the Office of Regulatory Compliance or through EthicsLine as outlined above.
The UCD Research Page also has a section dedicated to research participants. On that page is a mechanism to enable research participants to raise any questions or concerns by sending an e-mail to the Office of Regulatory Compliance.

**Monitoring and Auditing**

The CRSC conducts routine audits of research that does not otherwise have an outside monitor. Additionally, the QA team may, at the request of the Associate Vice Chancellor for Regulatory Compliance or the Director of the IRB, conduct an audit to confirm compliance with the IRB-approved protocol and any other regulatory requirements.

The CRSC conducts site initiation visits with new sponsor-investigators conducting research under the auspices of the COMIRB at UCD. This visit helps to assure that researchers have the necessary documentation and strategy to begin their studies. Subsequent visits will be made depending on the level of risk, complexity and experience of the sponsor-investigator at least once per year.

**Disciplinary Actions**

The IO or designee may place limitations or conditions on an investigator’s or research staff’s privilege to conduct Human Research whenever, in the opinion of the IO, such actions are required to maintain the Human Research Protection Program.

If the IO or designee does place such limits on a researcher or research protocol then this action will be communicated to the IRB of record, other regulatory committees within the HRPP, if applicable, the Dean of the School as well as appropriate Department Head and/or Division Chair. If the research is funded by a federal, state or foundation then Office of Grants and Contracts will be informed so that they can liaise with the appropriate funding agency as needed or the Clinical Trial Contracting Office will be informed so that appropriate communication can be coordinated with the industry sponsor.

**Approval and Revisions to the Plan**

This Human Research Protection Program Plan is approved by the Institutional Official. This Plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official or designee has the authority to amend this plan as deemed necessary.