



University of Colorado Denver
Human Research Protection Policies and Plan

Revised April 13, 2021

Approved by Associate Vice Chancellor for Regulatory Compliance: April 13, 2021



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Scope

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

Policy

The University of Colorado Denver I Anschutz Medical Campus (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.

University of Colorado Anschutz Medical Campus Chancellor and the University of Colorado Denver Chancellor have designated the Associate Vice Chancellor for Regulatory Compliance 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 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 a team of individuals at a research site conducts the Human Research, 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. In this document, references to the “Common Rule” and 45 CFR 46 refer to both the 2018 Requirements and the Pre-2018 Requirements unless otherwise noted. The applicability of the 2018 Requirements or the Pre-2018 Requirements to particular research are addressed where necessary in subsequent sections.

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.

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 D¹. 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.

¹ Quick applicability table for DHHS Subparts:

	DHHS	DOD	ED	EPA	VA
Subpart B	X	X		X	
Subpart C	X	X			X
Subpart D	X	X	X	X	X



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.

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 depends on the current active portfolio but may include:

- All forms of human subject research
- Research funded by DHHS or other federal agencies
- Other foundation or philanthropy 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.
- Investigator held Single Patient IND.
- 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 exception from informed 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

UCDenver and Anschutz Medical Campus Chancellors have 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 Chancellors have 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, to include Medicare Coverage Analysis,
- Export control,
- Regulatory compliance,
- HIPAA privacy and GDPR.

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 Health (UCHealth), Children's Hospital Colorado (CHCO), Denver Health and Hospital Authority (DHHA), and the VA Eastern Colorado Health Care System (VA ECHCS). An MOU is established between the IRB and each of these entities as well as other smaller institutions that routinely rely on COMIRB.

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 of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to 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 Boulder
- The IRB is a signatory to SMART IRB.
- The use of a central IRB is mandated by the funding agency.

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.

COMIRB Review for Non-Affiliated Institutions

COMIRB may review and approve a multi-site research project on behalf of a non-affiliated institution, so long as at least one of our affiliate institutions is engaged in the research.

The COMIRB Director will review the protocol or proposal prior to agreeing for COMIRB to serve as IRB of record for a non-affiliated institution. The IO will also be



consulted when the research activities at the non-affiliated institution pose more than minimal risk. COMIRB may choose to decline to serve as IRB of record for the non-affiliated institution if, for example, the research activities taking place at a non-affiliated institution involve INDs or IDEs, or the research involves complex clinical procedures. If the use of a single IRB is mandated by federal regulation and/or NIH policy, and COMIRB declines to serve as single IRB, an appropriate external IRB will be identified to serve as single IRB.

Non-affiliated institutions relying on COMIRB must enter into an IRB reliance agreement with the University (SmartIRB preferred) and provide any requisite documents to COMIRB (e.g., local context information, as necessary). The IRB reliance agreement will specify the individual research project conducted under the agreement and outline the duties and responsibilities of COMIRB and the non-affiliated institution and investigator.

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
- Material Transfer Agreements
- Pre-approval for UCD and the Affiliate hospitals
- Clinical Trials Management System, and other electronic regulatory support systems
- External IRB management
- ClinicalTrials.gov registration and record oversight
- Providing Medicare Coverage Analysis for clinical trials

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 thoughtful 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 an institutional scientific review committee of experienced investigators, and biostatisticians. The purpose of SARC is to evaluate the scientific merit of more than minimal risk 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 may undergo an expedited review process. Major scientific changes to a protocol post peer review, will also be reviewed by SARC.

Perinatal Research Facilitation Review Committee

The Perinatal Research Facilitation Review Committee is an institutional committee to facilitate research involving pregnant women and neonates. Pregnant women, their fetuses and newborn infants, especially preterm infants in neonatal intensive care units, represent a unique and limited population of families who would like to participate in clinical research. There is considerable potential for competition among studies that begin



at these unique stages of the life cycle, which is a burden to studies recruiting from these limited subject populations.

The Perinatal Research Facilitation Committee assists investigators whose studies involve:

- Pregnant women
- Placenta, umbilical cord or cord blood samples
- Neonates (0-30 days) admitted to the NICU or well-baby nursery at UCH, or the NICU, CICU, or PICU at CHCO

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.

Also, see CU Anschutz Policy to limit Conflicts of Interest between health care professionals and industry representatives, May 1, 2016

Institutional Conflict of Interest Management

UCD Institutional Conflict of Interest is governed by the University of Colorado "Conflicts of Interest and Commitment" policy. The COIC Office and Committee in accordance with their SOP operationalize it.

Also, see UCD policy AP 6008: Faculty Entrepreneurial Activity and SBIR/STTR Collaboration.

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. For protocols reviewed by an



external IRB, the external IRB team ensures IBC approval has been obtained prior to releasing the institutional approval.

Unanticipated problems that occur in these protocols require reporting to the COMIRB. 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 Export Control Officer in collaboration with the Institutional Biosafety Officer facilitates the requirements for the Institutional oversight of Dual Use Research of Concern (DURC). 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. The CIR will not approve the purchasing of the research product without documentation that it has IRB approval. Documentation of IRB review and approval is kept in the CIR 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. Any human subject’s research principal investigator who anticipates managing his or her own investigational products that will be used on the Anschutz Medical Campus or Denver Campus must submit a plan for review by the Investigational Product Review Committee.



CU Anschutz Research Pharmacy

A university-managed research pharmacy is anticipated to be established by October 2021 to augment the services provided by licensed affiliate pharmacies such as the UHealth Investigational Drug Service (IDS), Investigational Drug and Specialty Pharmacy Section of the Rocky Mountain Regional VA Medical Center, and Children’s Hospital of Colorado’s Research Pharmacy.

All study products must be managed by a hospital pharmacy or utilize the services of the CU Anschutz Research Pharmacy except for the following:

- Products categorized as medical devices
- Products classified as blood products
- Investigational products manufactured at CU Anschutz (e.g Gates Biomanufacturing Facility)
- Schedule 1 drugs

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.

Separate guidelines and policies will be established for use of hemp-derived products for use in human subject research to align with the 2018 Farm bill and related rules and regulations.

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.

GDPR Review Committee

The General Data Protection Regulation (GDPR) Committee will ensure all research involving European Economic Area (EEA) data is reviewed and documented to comply with GDPR. As needed, issues requiring escalation will be taken to the campus leadership.

The committee is responsible for reviewing, assessing and approving projects that include data that is subject to GDPR. The committee also ensures that the research teams comply with the policies and processes developed by CU Denver | Anschutz Medical Campus to comply with the GDPR requirements.



Membership: The Committee consists of representatives from the following departments:

Legal

Compliance and Privacy

COMIRB

IT and Security

And other experts as needed

The Associate Vice Chancellor for Regulatory Compliance will serve as Committee Chair

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 be reviewed by either 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 or CU Anschutz research pharmacy. The approval and recommendations of the IPRC must be in place before a study can enroll subjects.

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 FDA has approved the IND or IDE, the CRSC will provide ongoing support with submissions of amendments, and annual reports. CRSC staff track initial approval and annual report due dates for investigator-held and institution-held INDs and IDEs, including compassionate use drug and device approvals, in Oncore. CRSC staff send reminders to the IND/IDE holder prior to report due dates, and update Oncore records accordingly. 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.

CTOP

The Cellular Therapy Operations Program (CTOP) is a team of experienced clinical research professionals that support investigator-initiated clinical trials testing therapeutic agents produced at the Gates Biomanufacturing Facility (GBF).

CTOP works on behalf of CU Anschutz, acting as the sponsor team, and is comprised of a Scientific and Medical Director, Regulatory and Operations Director, Project Manager, Pharmacovigilance Specialist, and Protocol Development Specialist. The team works closely with the PI, study team, GBF, and the Office of Regulatory Compliance to develop and operationalize cell therapy clinical trials.

Clinical Trials Registration

The 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, and/or CMS ClinicalTrials.gov registration and reporting



requirements is responsible for posting the requisite information on the University's organizational account on ClinicalTrials.gov.

a) Registration Requirements

Registration is required when the study is:

1. An FDA-regulated Applicable Clinical Trial (ACT) as described by Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) and/or the implementing regulations at 42 CFR Part 11.
2. A clinical trial funded wholly or in part by the National Institutes of Health and subject to the [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#).
3. A Qualifying clinical trial, which will render claims for items and services to the Center for Medicare and Medicaid Services (CMS).
4. A clinical trial for which the investigators plan to publish results in an International Committee of Medical Journal Editors (ICMJE) member journal subject to the ICMJE [policy on clinical trials registration](#).
5. Otherwise required to be registered by the funding or supporting organization's policies (e.g. Bill and Melinda Gates Foundation; Welcome Trust).

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

FDAAA requires that the Responsible Party (or designee) for an ACT must submit required clinical trial information through the Protocol Registration and Results Reporting System (PRS) no later than 21 days after enrollment of the first participant. <https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa>

The NIH requires registration for all NIH-supported clinical trials, regardless of study phase, type of intervention, or whether or not they are subject to FDAAA. These studies must be registered no later than 21 days after enrollment of the first participant. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html>

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/>

b) Principal Investigator Responsibilities related to ClinicalTrial.gov Records

University researchers conducting investigator-initiated studies are responsible for the following:



- Ensuring that clinical trials are registered in a timely manner. Registration must occur within the timeframe set by FDAAA, NIH, and/or ICMJE, as applicable according to whichever timeframe is earliest.
- Reviewing the content of the clinical trial information posted on ClinicalTrials.gov for quality and accuracy.
- Reviewing the study record for inconsistencies and errors, and resolving outstanding “major” quality issues identified by ClinicalTrials.gov review staff.
- Ensuring that relevant updates to the information in the ClinicalTrials.gov record are made in a timely manner.
- Reviewing the clinical trial record periodically to verify that relevant study information is current and correct.
- If required, reporting tabular results data to ClinicalTrials.gov within 12 months of the primary completion date.

Registration information must be updated not less than once every 12 months unless the study status is “Completed”, “Terminated” or “Withdrawn”. Records should be updated at least once every 6 months while actively recruiting.

Some data elements, such as the Overall Recruitment Status, Primary and Study Completion Dates, and Responsible Party contact information, must be updated more rapidly if they change: usually within 30 days. https://clinicaltrials.gov/ct2/manage-recs/faq#fr_23

Additionally, if a study protocol is amended in such a manner that changes are communicated to the trial participants, the Principal Investigator must ensure that any relevant information in the record is updated accordingly within 30 calendar days after IRB approval.

c) Results Reporting

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

- The trial is an Applicable Clinical Trial (ACT) under FDAAA 801.
- The trial is NIH-supported, in whole or in part, and is subject to the [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#).
- The trial is registered on the University’s organizational account and is identified as an ACT or probable ACT (pACT) based on the information in the ClinicalTrials.gov study record.



Where required, reporting of aggregate results and adverse events to ClinicalTrials.gov must occur within 12 months of the Primary Completion Date, whether the study concluded according to the protocol or was terminated.

d) Support

The Clinical Research Support Center (CRSC) provides guidance, administrative support, and assistance in all aspects of clinical trials registration. When reviewing UCD faculty investigator initiated research, the 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 ClinicalTrials.gov. When notified, Principal Investigators and their designated study personnel contact the CRSC for help in setting up an account, setting up a record, and subsequent responses to reviews and other posting requirements.

Administrative support is available to assist researchers and study personnel with entering results.

Communication to constituents

Communication to the Principal Investigators and the broader research team is primarily via:

- CRSC monthly newsletter
- VC for Research's 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 but then broadened the range of external IRBs available in 2018

NCI CIRB is used by the UCD Cancer Center in accordance with NCI policies and procedures.

VA ECHCS uses the NCI CIRB for appropriate oncology protocols, the VA central IRB and other central IRBs when appropriate.

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 an external IRB. This mechanism will be considered for more than minimal risk research only as described earlier in this document.

Management and oversight of the external IRB process is by the external IRB coordinators. The External IRB team receives and reviews 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 UCHHealth 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 (CTMS):

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 CU Anschutz faculty. The same clinical trial management platform is used for human subject research involving procedures at CHCO, UCHHealth and DHHA.

Since April 2017, the CTMS platform has been required to include all human subject research involving procedures conducted on the Anschutz Medical Campus. To facilitate clinical trials billing compliance with UCHHealth, OnCore and Epic have been integrated. Also, see: CAP 6005 Utilization of OnCore for Clinical Research.

Biospecimen module (BSM)

As of September 2019, any studies that are collecting samples for future use must include a minimal data set in the BSM module of OnCore so that the samples can be tracked as part of the virtual centralized biobank initiative on the CU Anschutz campus.

eReg

As of January 2021, an electronic, part 11 compliance regulatory binder is available for research teams to utilize. The use of this system is required for any investigator initiated human subject research where the institution is sponsoring the IND or IDE.



Electronic Data Capture system (EDC)

As of January 2021, an electronic, part 11 compliance electronic data capture system is available for research teams to utilize. The use of this system is required for any investigator initiated human subject research where the institution is sponsoring the IND or IDE.

Insights

Insights is a web-based resource for use research teams and administrators that pulls OnCore data and provides a comprehensive view of their research portfolio. This tool enables the clinical research administration to evaluate research process as well as study team performance through standardized metrics. Insights allows research teams and the institution to identify low-accruing protocols, analyze study activation timelines, and track clinical trial financials.

Research Studies Recruitment

The research studies website: [Research Studies | School of Medicine | University of Colorado \(cuanschutz.edu\)](https://researchstudies.som.ucd.edu) is a public facing portal feed from OnCore to facilitate recruitment. Use of the standard research study page template does not need specific IRB approval but any variation must be approved in accordance with IRB policies and procedures.

The study becomes available on the website when the study is open to accrual in OnCore CTMS and is automatically removed when accrual is closed in the CTMS.

Evaluation of this initiative occurs at least annually.

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;

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.

The IO meets regularly (at least once a month) with each of the directors involved in the 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, VC for Research 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.

The resources directed to the HRPP are reviewed with the directors of each office on an on-going basis. Requests for additional resources or new initiatives are discussed with leadership in anticipation of the fiscal budget (July 1) each year.

Community partnerships with UCD

a) 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

b) 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

c) 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.

d) 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.

e) 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, VC for Research 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 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 to develop goals and activities under the mission of “Neighbors working together for healthy, vibrant communities. This partnership subsequently has transitioned to become The Office of Diversity, Equity, Inclusion and Community Engagement. This new office was established at CU Anschutz on July 1, 2020. Their work focuses on removing racist, biased, oppressive structural systems for underrepresented (URM), Black Indigenous and People of Color (BIPOC), and other vulnerable populations and stakeholders. The office has developed leadership councils, led forums and built partnerships with the Aurora and campus community, held education and training sessions, begun the process of collecting data on their efforts..

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 and /or CRAO (as assigned) has the responsibility to investigate allegations and findings of non-compliance and propose 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
- Web-based reporting system at www.ethicspoint.com.

EthicsPoint, an independent company, provides this reporting service. 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 Ethics Point 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 because of the reporting. Concerns about possible retaliation should be immediately reported to the IO or designee.

Ethics and Compliance webpage developed in 2018 to facilitate access to institutional and campus policies and facilitate feedback from faculty and staff:
<https://www.cuanschutz.edu/ethics-and-compliance>

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 Ethics Line as outlined above.

The UCD Research Studies: How do I get started web page also has a section describing how research participants can have their questions or concerns answered. On that page is the contact information to enable research participants to raise any questions or concerns by sending an e-mail to the Office of Regulatory Compliance or COMIRB: <https://researchstudies.cuanschutz.edu/Home/About>

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.



The IO also reviews audit reports conducted by the CU Anschutz Cancer Center DSMC and auditing program.

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.

The COMIRB Compliance Board makes recommendations to the IRB and/or the IO on compliance issues that occur in active human subject research conducted by university faculty at CU Anschutz or Denver or in situations where COMIRB is acting as the IRB of record.

Approval and Revisions to the Plan

The Institutional Official approves this Human Research Protection Program Plan. 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.