Table of Contents

Scope

Throughout this document "Organization" refers to Rocky Mountain University of Health Professions (RMUoHP).

Purpose

This Organization is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this 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 is based on all individuals in this Organization along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

Protocol approved before the implementation of the Revised Common Rule will be subject to the pre-2018 regulations. Protocols approved after the implementation of the Revised Common Rule will be subject to the 2018 regulations.

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.

Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this Organization.

Clinical Trial

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.[1] Only NIH funded clinical trials must be reported in ClinicalTrials.gov.

Engaged in Human Research

This Organization is engaged in Human Research when its faculty[2], students[3] or agents in furtherance of a research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

This Organization follows OHRP guidance on "Engagement of Institutions in Research" to apply this definition. Examples of what constitutes engaged and not engaged can be found in sections III A. and B. of the OHRP guidance document.

[1] https://grants.nih.gov/policy/clinical-trials/definition.htm

[2] University employees subject to University Policy Number 1125 on Faculty Scholarship Expectations or adjunct faculty members that voluntarily submit projects for review by the University's Institutional Review Board.

[3] Individuals enrolled in an academic degree program at the University working on a project to fulfill an academic requirement.

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

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- **Intervention** means physical procedures by which information or biospecimens 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 Private 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).
- **An identifiable biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

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.

Investigator

The person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial 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.[4]

[4] 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.

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.

Mission

The mission of this Organization's Human Research Protection Program 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, the Organization's institutional review boards (IRBs), IRB members and chairs, IRB staff, the Organizational official, and 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":

- Respect for Persons
- Beneficence
- Justice

Legal Requirements

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

All Human Research must undergo review by one of the organizationally designated IRBs. Activities that do not meet the definition of Human Research (e.g., classroom activities, quality improvement activities, program evaluation, and surveillance activities) do not require review and approval by one of the Organization's IRBs and do not need to be submitted to one of the Organization's IRBs unless there is a question regarding whether the activity is Human Research.
When this Organization is engaged in 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 should be referred to the IRB Office who will provide a determination.

Other Requirements

All Standard Operating 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."

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 the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D[5]. 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 the Department of Energy (DOE) O 443.1A and to use "Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with the Department of Energy (DOE) Requirements."

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.

When Human Research is subject to Veterans Administration (VA) oversight, this Organization commits to apply VHA Handbook 1200.05 requirements, which includes the requirement to apply 45 CFR §46 Subparts C and D, and all regulations pertaining to the participation of veterans as subjects including requirements for indemnification in case of research-related injury pertained to non-veteran subjects enrolled in Veterans Administration (VA) approved research.

Sponsored Human Research

For both sponsored and non-sponsored Human Research this Organization abides by its ethical principles, regulatory requirements and its Standard Operating Procedures.

[5] 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

Scope of Human Research Protection Program

All forms of human subjects research activity, whether funded or not-funded by the federal government, conducted by faculty, students, employees or agents of RMUoHP:

- For the purpose of completing an academic program at RMUoHP;
- In connection with their employment by RMUoHP; or
- At the direction of RMUoHP shall be subject to oversight by this Human Research Protection Program.

Human Research Protection Program Standard Operating Procedures

Standard Operating Procedures for the Human Research Protection Program are available on Canvas. The guest login and password are available on the Organization's website.

Human Research Protection Program Components

Organizational Official

The Executive Vice President of Academic Affairs/Provost (EVPAA/Provost) is designated as the Organizational Official.

The Organizational Official has the authority to take the following actions or delegate these authorities to a designee:

- Create the Human Research Protection Program budget.
- Allocate resources within the Human Research Protection Program budget.
- Appoint and remove IRB members and IRB chairs.
- Hire and fire research review staff.
- Determine what IRBs the Organization will rely upon.
- Approve and rescind authorization agreements for IRBs.
- Place limitations or conditions on an investigator or research staff's privilege to conduct Human Research.
- Create Standard Operating Procedures related to the Human Research Protection Program that are binding on the Organization.
- Suspend or terminate research approved by one of the Organization's IRBs.
- Disapprove research approved by one of the Organization's IRBs.

The Organizational Official has the responsibility to:

- 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 amendments as needed.
- Establish Standard Operating Procedures designed to increase the likelihood that Human Research is conducted in accordance with ethical and legal requirement.
- Institute regular, effective, 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 one of the IRBs designated by the Organization has not approved.
- 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 review, so that reviews are accomplished in a thorough and timely manner.
- Review and sign federal assurances (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.

All members of the Organization

All individuals within the Organization have the responsibility to:

- Be aware of 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 Organizational 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 Organizational Official.
- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.

Individuals who are responsible for business development are prohibited from carrying out day-to-day operations of the review process.

IRBs

The list of IRBs designated by the Organizational Official to be the IRBs relied upon by the Human Research Protection Program and the scope of review of these IRBs is listed in the IRB rosters available from the IRB Office.

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

- The IRBs are part 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.)

Reliance on an external IRB requires an Authorization Agreement for IRB review (AA) and a local review for compliance with local policies of the organization.

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.
- Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs' 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.

IRB members and IRB staff have the responsibility to follow Human Research Protection Program Standard Operating Procedures that apply to IRB members and staff.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in the INVESTIGATOR MANUAL.
- Follow the Human Research Protection Program Standard Operating Procedures.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Organizational Official.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the Organizational 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.

Directors of University Research, Program Directors, and Dissertation Committee Chairs

The Directors of University and Sponsored Research, Program Directors, and Dissertation Chairs have the responsibility to:

- Ensure that scholarly and/or clinical inquiry activities undertaken by faculty, employees, agents or students under their supervision are referred to a University IRB when the activity meets the federal regulatory definition of engaged in human subjects research.
- Make, in consultation with the IRB as needed, the determination that an activity meets the federal regulatory definition of engaged in human subjects research.
- Oversee the review and conduct of Human Research under their charge.
- Forward complaints and allegations regarding the Human Research Protection Program to the Organizational Official.
- Ensure that each Human Research study conducted under their charge has adequate resources.

Grants and Contracts

The IRB Office has the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program Standard Operating Procedures.

Education and Training

IRB members, IRB staff, investigators, research staff and others involved in the review or conduct of Human Research must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. (HRP-007 SOP: Investigator Human Subjects Research Training.) This training is valid for a three-year period, after which time the CITI

training program must be retaken. IRB staff also train IRB members on the Standard Operating Proceduress, checklists, and worksheets applicable to IRB members including regulatory and guidance requirements noted in the section "Other Requirements."

Questions and Additional Information for the IRB

The IRB Office wants your questions, information, and feedback. Contact and location information is:
Darcy Hammar, CIM
IRB Manager
Rocky Mountain University of Health Professions
122 East 1700 South, Building C
Provo, Utah 84606
Email: darcy.hammar@rm.edu
(801) 734-6770

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of 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 IRB Chair, IRB Office, Organizational Official (EVPAA/Provost), Legal Counsel, Director of Post-Professional Research, or Program Directors.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The Organizational Official has the responsibility to investigate all other reports and take corrective actions as needed.

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

To make such reports, contact:
Mark J. Horacek, PT, MS, PhD
Executive Vice President for Academic Affairs & Provost
Rocky Mountain University of Health Professions
122 East 1700 South
Provo, Utah 84606
801.734.6798
Email: mark.horacek@rm.edu

Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and organizational requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional. Random audits may also be conducted.

Disciplinary Actions

The Organizational Official, or the Organizational Official's designee, may take disciplinary action as specified in the Standard Operating Procedures against an investigator or research staff member whenever such actions are required to maintain the Human Research Protection Program.

Approval and Revisions to the Plan

This Human Research Protection Program Plan is to be approved by the Organizational Official (EVPAA/Provost). This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Organizational Official has the responsibility to review this plan to assess whether it is providing the desired results and has the authority to amend this plan as deemed necessary.

Approved:
Mark Horacek, PT, MS, PhD
Executive Vice President of Academic Affairs & Provost
January 21, 2019