



Human Research Protection Plan

Revised March 29, 2019



Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	2 of 13

Table of Contents

Scope.....	3
Purpose.....	3
Definitions.....	3
Agent.....	3
Clinical Trial.....	3
Engaged in Human Research.....	3
Human Research:.....	4
Human Subject as Defined by DHHS.....	4
Human Subject as Defined by FDA.....	4
Investigator.....	4
Research as Defined by DHHS.....	5
Research as Defined by FDA.....	5
Mission.....	5
Ethical Requirements.....	5
Legal Requirements.....	6
Other Requirements.....	6
Sponsored Human Research.....	7
Scope of Human Research Protection Plan.....	7
Human Subjects Protection Program Policies and Procedures.....	8
Components of the Human Research Protection Plan.....	8
Institutional Official.....	8
All members of the University.....	9
IRBs.....	10
Investigators and Research Staff.....	11
Legal Counsel.....	11
Deans/Department Chairs/Directors.....	11
Office of Sponsored Research and Programs.....	11
Education and Training.....	11
Questions and Additional Information for the IRB.....	12
Monitoring and Auditing.....	13
Disciplinary Actions.....	13
Approval and Revisions to the Plan.....	13



Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	3 of 13

Scope

Throughout this document “University” refers to Metropolitan State University of Denver.

Purpose

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

The University’s Human Research Protection Plan is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The Human Research Protection Plan relies on all individuals in this University along with key individuals and committees fulfilling their roles and responsibilities described in this plan. The University’s Human Subjects Protection Program (HSPP) serves as the administrative unit of this institutional plan to ensure that it functions effectively.

Definitions

Agent

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

An individual who is not an employee is considered an agent of this University for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of this University.

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

Clinical Trial

A biomedical 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 and effective.

Engaged in Human Research

In general, this University is considered engaged in Human Research when this University’s employees or agents for the purposes of the Human Research 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



Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	4 of 13

for the research. This University follows OHRP guidance on “Engagement of Institutions in Research”¹ to apply this definition and exceptions to 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).

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 (PI). At MSU

¹ <http://www.hhs.gov/ohrp/policy/engage08.html>



Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	5 of 13

Denver, the PI must be a faculty or staff member and only one PI will be recognized for each research protocol. Students who want to engage in Human Research must have a faculty or staff advisor involved in all aspects of their study, and the faculty or staff advisor must be designated as 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.²

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

Ethical Requirements

In the oversight of all Human Research, this University (including its investigators, research staff, students involved with the conduct of Human Research, the University’s Institutional Review Board (IRB), IRB members and chair, HSPP staff, the Institutional 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

² 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 Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	6 of 13

- Justice

Legal Requirements

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

All Human Research must undergo review by the University’s designated IRB. Activities that do not meet the definition of Human Research do not require review and approval by the University’s IRB and do not need to be submitted to the Human Subjects Protection Program unless there is a question regarding whether the activity is Human Research.

When this University 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 (45 CFR §46), the University commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When this University is engaged in FDA Human Research, this University 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 HSPP who will provide a determination.

Other Requirements

When reviewing research that involves community based research, the IRB obtains consultation or training.

All policies and procedures are applied identically to all research regardless of whether the research is funded or un-funded or is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review, and review of modifications to previously approved research
- Post-approval monitoring
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process and other language issues
- Ensuring all necessary approvals are met
- Coordination and communication with local IRBs

For clinical trials, this University commits to apply the “International Conference on Harmonisation – Good Clinical Practice E6.” (ICH-GCP)

This University 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.”)



Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	7 of 13

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

When Human Research is conducted or funded by the Department of Defense (DOD), this University 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.³ This University will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) Component supporting the research involving human subjects.

When Human Research is conducted or funded by the Department of Education (ED), this University 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 University 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 University 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 University abides by its ethical principles, regulatory requirements and its policies and procedures.

Scope of Human Research Protection Plan

The categories of Human Research overseen may include:

- International research
- Research conducted or funded by the Department of Defense (DOD)
- Research conducted or funded by the Department of Justice (DOJ)
- Research conducted or funded by the Department of Education (ED)
- Research conducted or funded by the Department of Energy (DOE)
- Research conducted, funded, or subject to oversight by the Environmental Protection Agency (EPA)
- Federally funded research

³ Quick applicability table for DHHS Subparts:

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

Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	8 of 13

- 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 that plans to or is likely to involve prisoners as subjects.
- Research involving children as subjects.
- 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 of consent documentation.

The categories of Human Research not overseen include:

- Research conducted or funded by the Veteran Administration (VA)
- Research involving fetuses.
- Research involving *in vitro* fertilization.
- Research involving non-viable neonates.
- Research involving neonates of uncertain viability.
- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director.
- Classified research.

Human Subjects Protection Program (HSPP) Policies and Procedures

Policies and procedures for the Human Subjects Protection Program are available on the following Web site: <http://www.msudenver.edu/irb/>.

Components of the Human Research Protection Plan

Institutional Official

The Associate Vice President of Curriculum and Academic Effectiveness is designated as the University's Institutional Official.

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

- Create the Human Subjects Protection Program budget.
- Allocate resources within the Human Subjects Protection Program budget.
- Appoint and remove IRB members and IRB chairs.
- Hire and fire research review staff.
- Determine what IRBs the University will rely upon.
- Approve and rescind authorization agreements for IRBs.

Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	9 of 13

- Place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research.
- Create policies and procedures related to the Human Subjects Protection Program that are binding on the University.
- Suspend or terminate research approved by the University's IRB.
- Disapprove research approved by the University's IRB.

The Institutional Official has the responsibility to:

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Subjects Protection Program.
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirement.
- Institute regular, effective, educational and training programs for all individuals involved with the conduct or oversight of Human Research.
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the University cannot approve research that has not been approved by the University's IRB or an IRB relied upon by the University.
- Implement a process to receive and act on complaints and allegations regarding the conduct or oversight of Human Research.
- 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 conduct or oversight of Human Research.
- Ensure that the Human Subjects Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, 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 University

All individuals within the University have the responsibility to:

- Be aware of the definition of Human Research.
- Consult the HSPP/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 Human Research or concerns about the Human Research Protection Plan, HSPP, or IRB to the Institutional Official.



Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	10 of 13

- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Plan to the HSPP/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 Institutional Official to be the IRBs relied upon in the Human Research Protection Plan and the scope of review of these IRBs are listed in the IRB rosters available from the HSPP.

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

- The IRBs are part of an AAHRPP accredited organization.
- This University'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 University 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 Institutional Agreement for IRB review (IAIR) and a local review for compliance with local policies of the organization.

The IRBs relied upon by this University have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the University. All Human Research must be approved by one of the IRBs designated by the Institutional Official. Officials of this University may not approve Human Research that has not been approved by the University's IRB.
- 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 HSPP staff have the responsibility to follow Human Subjects Protection Program policies and procedures that apply to IRB members and staff.



Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	11 of 13

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Subjects Protection Program requirements described in the INVESTIGATOR MANUAL (HRP-103).
- 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 Plan.
- Determine whether someone is acting as an agent of the University.
- 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/Directors

Deans, Department Chairs, and Directors have the responsibility to:

- Oversee the review and conduct of Human Research in their department or school.
- Forward complaints and allegations regarding the conduct or oversight of Human Research to the HSPP or the Institutional Official.
- Ensure that each Human Research study conducted in their department or school has adequate resources.

Office of Sponsored Research and Programs

The Office of Sponsored Research and Programs has the responsibility to review contracts and funding agreements for compliance with Human Subjects Protection Program policies and procedures.

Education and Training

All employees or agents of the University (faculty, staff, or students) who will be involved in Human Research are to review this plan prior to initiating research projects. The Institutional Official and HSPP staff are responsible for maintaining awareness of this policy.

IRB members, HSPP staff, and others involved in the review of Human Research must complete the online Collaborative Institutional Training Initiative (CITI) human subjects online training program. See the IRB website for a link to this training. This training is valid



Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	12 of 13

for a three-year period, after which time a refresher CITI course or additional training must be completed.

Investigators and research staff must complete the initial and continuing CITI human subjects online training described in the INVESTIGATOR MANUAL (HRP-103).

Questions and Additional Information for the IRB

The HSPP wants your questions, information, and feedback.

Contact information for the HSPP is:

Human Subjects Protection Program (HSPP)
P.O. Box 173362, Campus Box 48
Denver, CO 80217
Phone: 303-352-7330 (Michaela Clemens, HSPP Coordinator)
Email: hspp@msudenver.edu

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the conduct or oversight of Human Research may be reported orally or in writing. Individuals are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, HSPP staff, Institutional Official, 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 Institutional Official has the responsibility to investigate all other reports and take corrective actions as needed.

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

To make such reports, contact:

Dr. Chad Harris
Associate Vice President of Curriculum and Academic Effectiveness
P.O. Box 173362, Campus Box 48
Denver, CO 80217
Phone: 303-605-5282
Email: charr112@msudenver.edu



Human Research Protection Plan		
NUMBER	DATE	PAGE
HRP-101	5/29/2019	13 of 13

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 Institutional Official may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the Institutional Official such actions are required to maintain the Human Research Protection Plan.

Approval and Revisions to the Plan

This Human Research Protection Plan is to be approved by the University's President. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the Institutional Official, the University's President has the authority to amend this plan as deemed necessary.