



HEALTH
SCIENCES

OFFICE OF RESEARCH

Human Research Protection Program Plan¹

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¹ This document satisfies AAHRPP elements I.1.A-G, I-2, I-3, I.4.B-C, I.5.A, I.5.C, I.5.D, I.6.B, I.7.A, I.7.C, I-9, II.1.B, II.2.C, II.2.G, II.2.H, II.2.E-II.2.E.2, II.3.C-II.3.C.1, II.3.E, II.3.F, III.1.A, III.1.C, III.2.A, III.2.D

Human Research Protection Program Plan		
NUMBER	DATE	PAGE
HRP-101	02/28/2025	2 of 20

Table of Contents

Scope..... 3

Purpose..... 3

Definitions..... 3

 Agent..... 3

 Clinical Trial 3

 Engaged in Human Research 4

 Human Research: 4

 Human Subject as Defined by DHHS..... 4

 Human Subject as Defined by FDA..... 5

 Investigator 5

 Research as Defined by DHHS..... 5

 Research as Defined by FDA..... 5

Mission..... 6

 Ethical Requirements 6

 Legal Requirements 6

 Other Requirements 7

 Sponsored Human Research 8

 Human Research Protection Program Policies and Procedures..... 9

Human Research Protection Program Components..... 9

 Institutional Official..... 9

 Vice President for Research (Institutional Official’s Designee)..... 10

 All members of the Institution 12

 HRRCs 13

 Investigators and Research Staff..... 14

 Legal Counsel 14

 Deans/Department Chairs 15

 Sponsored Projects Office..... 15

 Investigational Drug Service..... 15

 Institutional Biosafety Committee (IBC)..... 16

 Conflict of Interest Committee (COIC) 16

 Human Use Subcommittee (HUS) of the Radiation Control Committee (RCC) 16

Monitoring and Auditing 17

Education and Training 17

Emergency Preparedness 18

Questions and Additional Information for the HRRC 18

Reporting and Management of Concerns 19

Disciplinary Actions 20

Approval and Revisions to the Plan..... 20

Human Research Protection Program Plan		
NUMBER	DATE	PAGE
HRP-101	02/28/2025	3 of 20

Scope

This document applies to all research involving human subjects conducted at the University of New Mexico Health Sciences Center (“UNM HSC” or “Institution”), including, but not limited to, student research, faculty research, clinical trials, sponsored research, and research conducted in collaboration with other institutions. The Institution’s Institutional Review Boards are referred to as the Human Research Review Committees (“HRRCs”).

Purpose

The UNM HSC is committed to protecting the rights and welfare of subjects in Human Research. The UNM HSC's Human Research Protection Program (HRPP) is a comprehensive system designed to protect the rights and welfare of human subjects in research. This document outlines the HRPP, detailing how the UNM HSC complies with ethical and legal requirements for conducting and overseeing human subjects research. The HRPP relies on the collective effort of all individuals within the UNM HSC, along with designated individuals and committees, who fulfill the roles and responsibilities described in this plan.

Definitions

Agent

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

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

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

Clinical Trial

A biomedical or behavioral research study involving human subjects designed to answer specific questions about diagnostic procedures or therapeutic interventions (drugs, biologic products, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are designed to determine whether new diagnostic procedures or therapeutic interventions are safe and efficacious. A research study is a clinical trial when 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. This definition is broad and includes almost all types of studies with human participants.

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	4 of 20

Engaged in Human Research

The UNM HSC is generally considered engaged in Human Research when its employees or agents, acting on behalf of the UNM HSC for research purposes, obtain: (1) data about human subjects through intervention or interaction with them; (2) identifiable private information about human subjects; or (3) informed consent from human subjects for the research. The UNM HSC adheres to the OHRP guidance on "Engagement of Institutions in Human Subjects Research" to determine when these criteria apply and when exceptions are appropriate. ²

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 or biospecimens through Intervention or Interaction with the individual, or (2) information or biospecimens that is both Private Information and Identifiable Information. For the purpose of this definition:

- **Intervention** means physical procedures by which data 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).

² <http://www.hhs.gov/ohrp/policy/engage08.html>

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	5 of 20

- **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).
- **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 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 who is the responsible leader of the team will 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.³

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

³ 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 Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	6 of 20

- 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 Institution's Human Research protection program plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by this Institution.

The UNM HSC aims to promote a culture of compliance with the highest legal and ethical standards for the conduct of human research. The institution is committed to the education of its research community and outreach to collaborating institutions as well as the community it serves.

Ethical Requirements

In the oversight of all Human Research, this Institution [including its investigators, research staff, students involved with the conduct of Human Research, the Institution's Human Research Review Committees (HRRCs), HRRC members and chairs, Human Research Protections Office (HRPO) 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
- Justice

Legal Requirements

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

All Human Research must undergo review by one of the Institutionally designated HRRCs. Activities that do not meet the definition of Human Research do not require review and approval by one of the Institution's Institutional Review Boards ("HRRCs") and do not need to be submitted to one of the Institution's HRRCs unless there is a question regarding whether the activity constitutes Human Research.

When this Institution 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

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	7 of 20

Common Rule, the Institution commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When this Institution is engaged in FDA Human Research, this Institution 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 Human Research Protections Office for review by the HRRC.

Other Requirements

When reviewing research that includes community-based research, the HRRC considers or seeks the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.

All policies and procedures are applied identically to all research regardless of whether the research 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
- UNM HSC does not conduct limited review.

When requested by a clinical trial sponsor, this Institution commits to compliance with the International Conference on Harmonisation – Good Clinical Practices (ICH-GCP) E6 to the extent ICH-GCP E6 is consistent with applicable federal regulations.

This Institution 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 research falls under the National Institute of Health (NIH) Single IRB Mandate for Multi-Site Research, this Institution follows the NIH policy. This policy established the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States.

Human Research Protection Program Plan		
NUMBER	DATE	PAGE
HRP-101	02/28/2025	8 of 20

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

When Human Research is conducted or funded by the Department of Defense (DOD), this Institution commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D⁴. This Institution 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 Institution 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 Institution 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 Institution 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 the European Union General Data Protection Regulations (GDPR), this Institution coordinates with legal counsel to ensure that the research activities conform to broader institutional policies related to GDPR, where applicable, as well as legal counsel’s interpretation of study-specific GDPR requirements.

Sponsored Human Research

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

⁴ 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 Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	9 of 20

Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program Plan are available on the Human Research Protections Office website:

<https://hsc.unm.edu/research/compliance/hrpo/hrpp.html>

Human Research Protection Program Components

Institutional Official

The Executive Vice President for HSC is designated as the Institutional Official.

The Institutional 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 HRRC members and HRRC chairs.
- Hire and terminate HRPO staff, consistent with UNM Human Resources policies and procedures.
- Determine what HRRCs the Institution will rely upon. In this regard the Institutional Official has the authority to determine whether the University may rely on any one or more external IRBs or central IRBs.
- 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 Human Research Protection Program and the HRPO that are binding on the Institution.
- Suspend or terminate HRRC approval of research.
- Disapprove research approved by the HRRC.
- Establish a contingency plan for transferring oversight of one or more studies to another institution or IRB in the event the HRRC is unable to continue oversight of the studies in an emergency/disaster scenario (e.g., natural disasters, man-made disasters, infectious disease pandemics, etc.).

The Institutional Official has the responsibility to:

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	10 of 20

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
- Periodically review the University's Human Research Protections plan to assess whether it is providing the desired results and implement amendments or changes as needed.
- Establish policies and procedures designed to ensure 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 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 Institution cannot approve research that has not been approved by an HRRC designated by the Institution.
- Ensure that the HRRC Chair(s) and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the HRRC.
- Implement a process to receive and act on complaints and allegations regarding the conduct of our Human Research Protection Program.
- Follow-up on findings of serious non-compliance of HRPO Staff and HRRC Members.
- 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, 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.

Vice President for Research (Institutional Official's Designee)

The Institutional Official has delegated to the Vice President for Research the following authorities:

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	11 of 20

- Appointing HRRC members. If the Vice President for Research determines to not renew, or to suspend or terminate, the HRRC membership of any individual for whom it has been determined that he/she is not fulfilling membership responsibilities and or obligations, the Vice President for Research shall first consult with the HRRC Executive Chair, and shall inform the Institutional Official in writing of the decision to include a written justification for the decision;
- Appointing the HRRC chair or co-chairs. If the Vice President for Research determines to not renew, or to suspend or terminate, one or more HRRC Chairs for whom it has been determined that he/she is not fulfilling such Chair's responsibilities and or obligations, the Vice President for Research shall first consult with the HRRC Executive Chair, and shall inform the Institutional Official in writing of the decision to include a written justification for the decision;
- Performing periodic evaluation of the performance of the HRRC Executive Chair and the individual HRRC Chairs and administrative staff. In this connection, the HRPO and its staff shall report administratively to the HSC Office of Research under the auspices of the Vice President for Research;
- Managing and administering funds and ensuring that adequate personnel, space and other resources are allocated to the Human Research Protections Program. In this connection, in the preparation of the annual budget for the HRPO and the HRRC, the Vice President for Research will consult with the Executive Research Operations Officer of the Office of Research, the Office of Research Operations Manager, the HRPP Director and the HRRC Executive Chair as to budget and financial needs, which views shall, as a part of the UNM Health Sciences normal budgeting processes, be communicated to the Senior Executive Financial Officer for the UNM Health Sciences;
- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other Institutions, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements). In this connection, the Vice President for Research is delegated authority and responsibility to determine whether or not the University may rely on one or more external IRBs and/or central IRBs and to sign all documents and instruments as may be necessary to carry out this determination, consistent with the provisions of the *HRP-103: Investigator Manual*;
- Being the point of contact for correspondence addressing human subjects research with the OHRP, the FDA and other agencies as applicable, including reports to federal agencies;

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	12 of 20

- Ensuring that HRRC members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Developing and implementing an initial and continuing educational plan for HRRC members, staff and investigators. The Institutional Official anticipates and expects that the Vice President for Research will consult and collaborate with the HRRC Chairs, and appropriate individuals in the Office of Research (which includes the HRPO) in developing and implementing those educational plans;
- Recruiting qualified members that encompass adequate expert, non-scientific and unaffiliated representation on the HRRCs. The Institutional Official anticipates and expects that the Vice President for Research will consult and collaborate with the HRRC Chairs, and appropriate individuals in the Office of Research (which includes the HRPO) in developing and implementing such a recruitment plan;
- Reviewing and approving Standard Operating Procedures (SOPs) for the HRRCs and the HRPO;
- Overseeing daily operations of the HRRCs and the HRPO in accordance with the SOPs. In this connection, The Vice President for Research has been tasked with establishing, in consultation with the HRRC Executive Chair, metrics and benchmarking statistics to ascertain the operational performance of the HRRCs, the HRPO and the HRPO staff including processing timelines and productivity reporting, which shall be reported to the Institutional Official on a semi-annual basis. Additionally, the Vice President for Research shall report to the Institutional Official the results of compliance oversight reviews of the HRPO and the HRRCs that are or may be conducted by the UNM HSC Compliance Office.

All members of the Institution

All individuals within the Institution have the responsibility to:

- Be aware of the definition of Human Research.
- Consult the HRRC 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 HRRC 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 HRRC Executive Chair, the Executive Research Operations Officer, the HRPP Director, the Vice President for Research or the Office of University Counsel.

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	13 of 20

Concerns relative to undue influence may also be reported anonymously to the HSC's Compliance Hotline at (888) 899-6092, or through the EthicsPoint Hotline at unm.ethicspoint.com.

- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the HRRC.

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

HRRCs

The list of HRRCs designated by the Institutional Official to be the HRRCs relied upon by the Human Research Protection Program and the scope of review of these HRRCs is included in the IRB rosters available from the Human Research Protections Office.

This Institution may rely upon IRBs of another Institution with the approval of the Vice President for Research.

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

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

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution. All Human Research must be approved by one of the IRBs designated by the Institutional Official. Officials of this Institution may not approve Human Research that has not been approved by one of the Institution's IRBs.
- 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.

HRRC chairs, members and HRPO staff have the responsibility to follow Human Research Protection Program policies and procedures.

Human Research Protection Program Plan		
NUMBER	DATE	PAGE
HRP-101	02/28/2025	14 of 20

Quality Improvement Program

The goal of the quality improvement program is to achieve and maintain compliance and to achieve targeted levels of quality, efficiency and effectiveness of the HRPP.

Objectives of the quality improvement program are to:

- Improve compliance of investigators with their regulatory and institutional responsibilities.
- Improve compliance of minutes with applicable regulations.
- Increase efficiency of recording and finalizing minutes.

The Investigator Quality Improvement Assessment tool used by the HRPP is designed to help researchers adhere to good clinical practices, maintain compliance with research regulations, retain an organized system for records management, and assist with collection of credible, high quality research data. Results from this assessment are tracked and used to develop focused education and training programs for investigators.

The Minutes Quality Improvement Assessment tool used by the HRPP is designed to help HRPO staff members consistently and accurately document the deliberations and determinations of the HRRCs and other regulatory requirements. Results from this assessment are tracked and used to identify areas for staff education and training.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in the INVESTIGATOR MANUAL (HRP-103).
- Comply with all determinations and additional requirements of the HRRC, the HRRC chair, and the Institutional Official.
- Develop and implement emergency/disaster response procedures for their research depending on location and nature of the research.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the Institutional Official, HRRC, and other individuals involved with the Human Research Protection Program.
- Determine whether someone is acting as an agent of the Institution.

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	15 of 20

- 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 study conducted in their department or school has adequate resources.
- Conduct preliminary scientific/scholarly review of human research studies prior to submission to HRRC.

Sponsored Projects Office

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

Investigational Drug Service

It is the policy of UNM HSC to establish and follow a standardized procedure for the use of investigational drugs in humans that is in compliance with all applicable regulations governing the custody and distribution of investigational drugs. It is the policy of UNM HSC that all investigational protocols utilizing drugs will be under the administrative control of the UNMHSC Pharmacy Department and approved affiliates. For each UNM HSC area that provides investigational drug protocol services, the lead pharmacist will be qualified and responsible for determining how each protocol is to be administered.

To ensure appropriate oversight of investigational drugs used in human research:

- A.** The Institution’s pharmacist shall conduct, participate in and support medical and pharmaceutical research appropriate to the goals, objectives and resources of the Institution.
- B.** There shall be a pharmacist member on the HRRC. The pharmacist shall ensure that policies and procedures for the appropriate use of investigational drugs are established and followed.

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	16 of 20

C. A copy of the research protocol for a study involving investigational drugs and the Institution's patients, shall be provided to the pharmacist. A copy of drug protocols shall be maintained in the pharmacy of all active investigational drug studies and similar research projects involving drugs in which the facility's patients are participants.

Institutional Biosafety Committee (IBC)

The IBC reviews and approves research using specific biological agents and recombinant or synthetic nucleic acid molecule experiments covered under the NIH Guidelines. As part of the review process the IBC evaluates: the experience and training of the researchers, practices and procedures, containment equipment, facility design, infection control practices, biological waste management, post exposure prophylaxis and medical surveillance. Studies requiring IBC and IRB review will not be initiated until compliance committee approvals have been obtained by the IBC and HRRC.

Conflict of Interest Committee (COIC)

Any actual or perceived conflict of interest as defined by institutional policy, consistent with applicable federal and state regulations is required to be reported to and reviewed by the Conflict of Interest Committee (COIC). The COIC will inform the HRRC when investigators conducting human research have significant financial interests that constitute a financial conflict of interest. The COI review determination and management plan, if applicable, will be considered as part of the final HRRC determination for approval of research. The HRRC may accept the plan as sufficient, add requirements to the management plan, or determine that the conflict and/or management plan is such that the research cannot be approved as proposed (see SOP: FINANCIAL CONFLICTS OF INTEREST [HRP-055]). Should the HRRC or the Conflict of Interest Committee require changes in the research study plan to mitigate a conflict, the Principal Investigator will be required to submit the revised documents for HRRC review and approval.

Human Use Subcommittee (HUS) of the Radiation Control Committee (RCC)

The Human Use Subcommittee (HUS) reviews all protocols involving radiation exposure to normal subjects, and/or to clinical human subjects when the exposure is considered standard-of-care or experimental. If appropriate, the HUS may approve the protocol, or it may refer the protocol to the full Radiation Control Committee (RCC) for more extensive review.

Examples of procedures which must be reviewed and approved by the HUS include, but are not limited to:

- (i) Any radiation exposures to normal subjects;
- (ii) Any use of an investigational radiation device;

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	17 of 20

- (iii) Any use of an investigational radiopharmaceutical or investigational implant/seed;
- (iv) Any use of an investigational contrast medium with radiation;
- (v) Any use of imaging **where it is the subject of the investigation**, such as special CT sequences to guide a new surgical procedure.

Monitoring and Auditing

The HRPO staff will conduct routine onsite review and/or monitoring, as well as directed (for-cause) audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional.

Education and Training

To maintain awareness of HRPP policies and procedures, new information, revised materials and opportunities for continuing education are communicated to the research community by way of various email list-serve groups targeted to appropriate audiences.

HRRC members, HRPO staff, and others involved in the review of Human Research must complete initial and continuing training utilizing the Collaborative Institutional Training Initiative (CITI) human subjects online training program. Training is valid for a three-year period, after which time refresher training must be completed.

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

HRRC members must satisfy training requirements as defined in SOP: HRRC MEMBERSHIP APPOINTMENT AND TERMS (HRP-082).

HRPP staff will coordinate with organizational officials in the development and implementation of training materials related to emergency preparedness and response plans specific to human research conducted at the organization. The HRPP emergency preparedness plan will be made available to the human research community via the IRB website. The organization is responsible for notifying research teams when the organization's emergency response plan is activated.

Additional support is provided to investigators and research staff in the form of 1-on-1 or group consultations and educational sessions for the classroom or for departments through the HRPO IRB-on-the-Go Specialist.

Human Research Protection Program Plan		
NUMBER	DATE	PAGE
HRP-101	02/28/2025	18 of 20

Emergency Preparedness

The organization routinely assesses potential emergency scenarios and threats to the institution to improve its emergency preparedness and response plan. The HRPP Director, or their designee, collaborates with organizational leadership to develop, implement, and assess, emergency preparedness procedures for the HRPP.

Depending on the nature of the event, the HRPP Director will collaborate with institutional leadership to determine the types of research that might continue and the types that the institution may need to temporarily postpone. The organization proactively identifies external IRBs on which it can rely on temporarily during an emergency.

The HRPO staff will work with IT resources and/or electronic system vendors to ensure continuity of operations in the event that electronic systems are inaccessible or not operational for extended periods of time during an emergency/disaster. The HRPP Director will collaborate with the vendor of the HRRC’s electronic system to ensure that records are maintained on a secure server that is accessible in the event of an emergency.

The organization will implement alternative review procedures, including leveraging online and virtual platforms, to ensure that HRRC meetings can continue in scenarios where the HRRC cannot meet in person. In instances where the convened HRRC is unable to meet and HRRC approval for a study may lapse, the HRRC Chair can determine whether subjects can continue to participate in research activities if it is in the best interest of already enrolled subjects.

Questions and Additional Information for the HRRC

The Human Research Protections Office (HRPO) welcomes the research community’s questions, information, and feedback.

Contact and location information for the HRPO is:

Brad Dolin, JD
 HRPP Director
 University of New Mexico Health Science
 Reginald Heber Fitz Hall, B71
 Albuquerque, New Mexico 87131
 Email: HSC-HRPO@salud.unm.edu
 (505) 272-1129

Human Research Protection Program Plan

NUMBER	DATE	PAGE
HRP-101	02/28/2025	19 of 20

Reporting and Management of Concerns

The University of New Mexico is fully committed to ensuring the autonomy of the HRRCs in exercising their decision-making and other responsibilities for the review of research as delegated to them above. Individual HRRC Reviewers, whether employed by the University or affiliate or community reviewers, have both the obligation and right to report any attempts at undue influence upon them to make decisions with respect to matters, actions, or decisions within the delegated authority of the HRRCs (as described above). "Undue influence" refers to interference with the normal functioning and decision-making of an HRRC in order to secure a particular determination or outcome.

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, in person or in writing, to the HRRC Executive Chair, the Executive Research Operations Officer, the HRPP Director, the Vice President for Research, or the Office of University Counsel. Concerns relative to undue influence may also be reported anonymously to the HSC's Compliance Hotline at (888) 899-6092, or through the EthicsPoint Hotline at unm.ethicspoint.com.

The HRRC 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 who report in good faith possible compliance issues should not be subjected to retaliation or harassment as a result of the reporting (Reference University Administrative Policy 2200). Concerns about possible retaliation should be immediately reported to the University of New Mexico Internal Audit Department.

To make such reports, contact:

University of New Mexico
Internal Audit Department
1801 Roma NE
Albuquerque, New Mexico 87131-0001
(505) 277-5016

Concerns may also be reported anonymously to the HSC's Compliance Hotline at (888) 899-6092, or through the EthicsPoint Hotline at unm.ethicspoint.com.

Human Research Protection Program Plan		
NUMBER	DATE	PAGE
HRP-101	02/28/2025	20 of 20

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 ensure the protection of human subjects in research and maintain the Human Research Protection Program.

Approval and Revisions to the Plan

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