# Human Research Protection Program Plan

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-101</td>
<td>01/01/2015</td>
<td>2 of 29</td>
</tr>
</tbody>
</table>

## Table of Contents

- Scope ........................................................................................................... 4
- Purpose ......................................................................................................... 4
- Definitions .................................................................................................... 4
  - Agent ........................................................................................................ 4
  - Clinical Trial ............................................................................................. 4
  - Engaged in Human Research ..................................................................... 4
  - Human Research: ...................................................................................... 5
  - Human Subject as Defined by DHHS ....................................................... 5
  - Human Subject as Defined by FDA ......................................................... 5
  - Investigator .............................................................................................. 5
  - Research as Defined by DHHS ................................................................. 6
  - Research as Defined by FDA ................................................................. 6
- Mission ......................................................................................................... 6
- Ethical Requirements .................................................................................... 6
- Legal Requirements ..................................................................................... 7
- Other Requirements ...................................................................................... 7
- Sponsored Human Research ........................................................................ 9
- Scope of Human Research Protection Program ......................................... 9
- Human Research Protection Program Policies and Procedures ................. 9

## Human Research Protection Program Components ........................................ 9

- Institutional Official .................................................................................... 9
- Vice Chancellor for Research (Institutional Official’s Designee) ................. 10
- Veterans Administration (VA) Facility Director .......................................... 12
- Veterans Administration (VA) Research Compliance Officer (RCO) ........... 17
- Veterans Administration (VA) Privacy Officer and the Information Security Officer .... 18
- All members of the Organization ................................................................ 19
- HRRCs ......................................................................................................... 19
- Investigators and Research Staff ................................................................. 20
- Legal Counsel .............................................................................................. 21
- Deans/Department Chairs ........................................................................... 21
- Sponsored Projects Office .......................................................................... 21
- Investigational Drug Service ....................................................................... 21
- Institutional Biosafety Committee ............................................................ 22
- Conflict of Interest Committee (COIC) ...................................................... 22
- Human Use Subcommittee (HUS) of the Radiation Control Committee (RCC) .... 22
- Research and Development Committee (VA) ............................................ 23
- Monitoring and Auditing ........................................................................... 23
- Education and Training .............................................................................. 23
- Education and Training for Veterans Administration (VA) Research .......... 23
- Treatment of Research-Related Injuries to Human Subjects at Veterans Administration (VA) Facilities ................................................................. 25
- Credentialing and Privileging for Research at Veterans Administration (VA) Facilities ................................................................. 26
Human Research Protection Program Plan

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-101</td>
<td>01/01/2015</td>
<td>3 of 29</td>
</tr>
</tbody>
</table>

Student and Other Trainee Research at Veterans Administration (VA) Facilities .................. 27
Questions and Additional Information for the HRRC ....................................................... 27
(505) 272-1129 Reporting and Management of Concerns .................................................. 28
Disciplinary Actions ................................................................................................. 28
Approval and Revisions to the Plan ........................................................................... 29
**Scope**
Throughout this document “Organization” refers to the University of New Mexico Health Sciences Center (UNM HSC).

**Purpose**
The UNM HSC 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.

**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**
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 Organization is considered engaged in Human Research when this Organization’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 for the research. This Organization follows OHRP guidance on “Engagement of Institutions in Research”¹ to apply this definition and exceptions to this definition.

¹ [http://www.hhs.gov/ohrp/policy/engage08.html](http://www.hhs.gov/ohrp/policy/engage08.html)
# Human Research Protection Program Plan

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-101</td>
<td>01/01/2015</td>
<td>5 of 29</td>
</tr>
</tbody>
</table>

## 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 who is the responsible leader of the team will be called the principal investigator.
Human Research Protection Program Plan

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-101</td>
<td>01/01/2015</td>
<td>6 of 29</td>
</tr>
</tbody>
</table>

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 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.

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.

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 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

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.
Legal Requirements

This Organization voluntarily 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 HRRCs. Activities that do not meet the definition of Human Research do not require review and approval by one of the Organization’s HRRCs and do not need to be submitted to one of the Organization’s HRRCs unless there is a question regarding whether the activity is Human Research.

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

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

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the Human Research Protections Office for review by the HRRC.

Other Requirements

When reviewing research that involves community based research, the HRRC considers 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
When requested by a clinical trial sponsor, the Organization voluntarily commits to compliance with ICH-GCP E6 to the extent ICH-GCP E6 is consistent with applicable federal 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 the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D. This Organization 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 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.

---

3 Quick applicability table for DHHS Subparts:

<table>
<thead>
<tr>
<th></th>
<th>DHHS</th>
<th>DOD</th>
<th>ED</th>
<th>EPA</th>
<th>VA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subpart B</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subpart C</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Subpart D</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
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 policies and procedures.

Scope of Human Research Protection Program
The categories of Human Research overseen include:
- All forms of human research
- 

Human Research Protection Program Policies and Procedures

Human Research Protection Program Components

Institutional Official
The Chancellor for Health Sciences 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 fire HRPO staff, consistent with UNM Human Resources policies and procedures.
- Determine what HRRCs the Organization 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 Organization.
- Suspend or terminate HRRC approval of research.
- Disapprove research approved by the HRRC, as set forth in the HRRC Manual.

The Institutional Official has the responsibility to:
Human Research Protection Program Plan

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-101</td>
<td>01/01/15</td>
<td>10</td>
</tr>
</tbody>
</table>

- 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 Organization cannot approve research that has not been approved by an HRRC designated by the Organization.
- Implement a process to receive and act on complaints and allegations regarding the conduct of our 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, 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 Chancellor for Research (Institutional Official’s Designee)

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

- Appointing HRRC members. If the Vice Chancellor 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 Chancellor for Research shall first consult with the HRRC Executive Chair, and shall inform me in writing of the decision to include a written justification for the decision;
- Appointing the HRRC chair or co-chairs. If the Vice Chancellor for Research determines to not renew, or to suspend or terminate, one or more IHRRC Chairs for whom it has been determined that he/she is not fulfilling such Chair’s responsibilities and or obligations, the Vice Chancellor for Research shall first consult with the HRRC Executive Chair, and shall inform me 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 Chancellor 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 Chancellor 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 Center normal budgeting processes, be communicated to me and the Senior Executive Financial Officer for the UNM Health Sciences Center;

- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, 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 Chancellor 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 necessary 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;

- 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. I would anticipate and expect that the Vice Chancellor for Research would 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. I would anticipate and expect that the Vice Chancellor for Research would 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, I have asked the Vice Chancellor for Research to establish, in consultation with the HRRC Executive Chair, metrics and benchmarking statistics to ascertain the operational performance of the HRRCs, the HRPO and the HRRC staff including processing timelines and productivity reporting, which shall be reported to me on a semi-annual basis. Additionally, the Vice Chancellor for Research shall report to me the results of compliance oversight reviews of the HRPO and the HRRCs that are or may be conducted by the UNM HSC Compliance Office.
Veterans Administration (VA) Facility Director

The VA Facility Director is responsible for overseeing the creation and implementation of an HRPP for research involving human subjects or human biological specimens commensurate with this facility, the resources of this facility, and the size and complexity of the research program at this facility.

VA Facility Director is responsible to:

- Oversee the IRB, R&D Committee, research office, and all investigators and research team members who perform human research at this facility.
- Delegate authority in writing for all respective roles and responsibilities within this facility’s HRPP to provide the Organizational structure and ensure accountable leadership for compliance oversight activities for all human subjects research conducted at the facility.
- Create and implement initial and continuing education programs.
- Ensure that any IRB designated as an IRB of record for this VA facility is established in accordance with the requirements of this Handbook and 38 CFR 16.103(b)(2); registered with OHRP and, if appropriate, FDA; and listed as an IRB of record on this VA facility’s federalwide assurances (FWA). The IRB of record may include this facility’s own IRB, the VA Central IRB, the IRB of another VA facility, or an IRB established by an affiliated medical or dental school. Neither this VA facility nor the investigator may engage the services of another IRB for the purposes of avoiding the rulings of the IRB of record. Under exceptional circumstances, this VA facility may request a waiver from the CRADO to utilize the services of an IRB operated by another Federal department or agency that is signatory to the Common Rule. This VA facility’s own internal IRB cannot serve as an IRB of record for any non-VA entity except a Department of Defense (DOD) facility or a VA nonprofit research and educational foundation. VA nonprofit research and education foundations must have an IRB of record of this VA facility, whether the IRB is this VA facility’s own internal IRB, another VA facility’s IRB, the VA Central IRB, or its academic affiliate’s IRB.
- Ensure that the IRB of record functions independently, and that its Chair, or Co-Chairs, and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the IRB.
- Ensure provision of adequate resources to support the operations of HRPP so that those operations are in compliance with all VA and other Federal requirements that govern human subjects research protection. These resources include, but are not limited to:
  - Administrative resources for meeting space and sufficient staff to support IRB’s review and recordkeeping duties (38 CFR 16.103(b)(2)). The meeting space needs to be sufficient to provide privacy for conducting IRB meetings, other sensitive duties, and secure storage of records. The resources also need to include adequate administrative personnel, equipment, and space for the local research office.
  - Appropriate human subjects protection educational opportunities for IRB members, relevant administrative staff, and all members of the research team.
- Ensure that IRB members, relevant administrative staff, and all members of the VA research team are appropriately knowledgeable to fulfill their respective duties in accordance with ethical standards and all applicable local, VA and other Federal requirements.
- Ensure that VA human subjects protection training requirements are met.
- Develop local SOPs, to provide documentation that the biennial requirements are met for Good Clinical Practices, and to conduct training the ethical principles in which human studies research is conducted.
- Be the point of contact for correspondence addressing human subjects research with OHRP, FDA, and VHA Central Office.
- Ensure this VA facility’s HRPP is accredited by an Organization approved by ORD to perform this function.
- Certify that all personnel involved in research including, but not limited to, research office staff, investigators, and other research team members have appropriate credentials and privileges (when applicable) to perform their human research-related duties.
- Ensure a local Research Subject Outreach Program is implemented to include:
  - A reliable mechanism for research subjects to communicate with research study investigators and with an informed VA representative who is independent of the research study in question (e.g., providing contact information in the informed consent form).
  - That investigators make every reasonable effort to provide the informational brochure, “Volunteering in Research – Here Are Some Things You Need To Know,” [http://www.research.va.gov/programs/pride/veterans/tri-fold.pdf](http://www.research.va.gov/programs/pride/veterans/tri-fold.pdf) to potential research subjects in settings where subjects may be recruited (e.g., clinic waiting areas), and to each prospective subject when that individual is approached to take part in a study.
  - Venues for research subjects and their designated representatives to obtain information, discuss their questions and concerns, and offer their input.
  - When appropriate, educational activities suitable for research subjects and their communities.
- Ensure that recruiting documents, flyers, and advertisements for non-VA research are not posted within or on the premises of this VA facility. Posting of such documents may give the Veteran or visitors to this VA facility the impression that the non-VA study is VA-approved research, the VA supports or endorses the research, or that VA will pay for the research expenses that are incurred. General guidance may be posted within VA indicating that Veterans may speak with their health care providers if they wish to participate in research and that information on clinical trials is available at: [http://clinicaltrials.gov](http://clinicaltrials.gov).
- Ensure appropriate auditing of local human subjects research studies to assess compliance with all applicable local, VA, and other Federal requirements including, but not limited to, ORO requirements.
Human Research Protection Program Plan

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-101</td>
<td>01/01/2015</td>
<td>14</td>
</tr>
</tbody>
</table>

- Each VA-approved human subjects research study must be completely audited in accordance with VHA Handbook 1058.01.
- Each study must be audited for compliance with the regulations and policies on informed consent in accordance with VHA Handbook 1058.01.
- Approve the request for permission to conduct international research at this VA facility and ensuring CRADO approval of international research is obtained prior to its initiation at the facility.
- Fulfill educational requirements mandated by VA Office of Research and Development and OHRP.
- Unless a waiver for a part-time research compliance officer is approved by the VA Under Secretary for Health, appoint at least one full-time research compliance officer to conduct annual research consent document audits and triennial regulatory audits, and to assist in VA assessments of regulatory compliance.
- Report any appointment, resignation, or change in status of this VA facility's research compliance officer to Office of Research Oversight (ORO) and VHA Central Office, with a copy to the relevant Office of Research Oversight (ORO) research officer, within 10 business days after the appointment, resignation, or change takes effect.
- Report in writing to Office of Research Oversight (ORO) Research Officer, with a simultaneous copy to the VISN director, the Office of Research and Development (ORD), Associate Chief of Staff for Research, the Research and Development Committee, any relevant research review committees, and the Research Compliance Officer within five business days after being notified of a research problem or event (including Serious or Continuing Non-Compliance, apparent Serious Non-Compliance or Continuing Non-Compliance, an Unanticipated Problem Involving Risks to Subjects or Others, a Suspension of IRB Approval, or Termination of IRB Approval) for which such reporting is required under VHA Handbook 1058.01 unless already reported. A written report is required regardless of whether disposition of the event has been resolved at the time of the report. Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant Office of Research Oversight (ORO) at intervals and in a manner specified by that office.
- Provide a copy of any Office of Research Oversight (ORO) compliance reports regarding the research program to the associate chief of staff for research, Research and Development Committee, any relevant research review committees, and the research compliance officer in a timely fashion.
- Report the following research events to Office of Research Oversight (ORO) Central Office, with a simultaneous copy to the appropriate Office of Research Oversight (ORO) Research Officer, as indicated in the following:
  - IRB Changes:
    - The proposed addition or removal of the IRB of record designated in this VA facility’s federalwide assurances (FWA) must be submitted to ORO Central Office prior to submission to OHRP and in accordance with VHA Handbook 1058.03.
Human Research Protection Program Plan

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-101</td>
<td>01/01/2015</td>
<td>15</td>
</tr>
</tbody>
</table>

- Any change in IRB membership rosters must be reported to ORO Central Office in accordance with VHA Handbook 1058.03.
  - Substantive Memorandum of Understanding Changes:
    - Any substantive change in a Memorandum of Understanding with an affiliate institution or other entity related to the designation of IRB or other human research protection arrangements must be reported to ORO Central Office within five business days.
  - Accreditation Problems:
    - Failure of this VA facility to achieve the accreditation status required by the Office of Research and Development (ORD) for human research protections, any change in this VA facility’s accreditation status, or any change in the accreditation status of an affiliate involved in this VA facility’s HRPP must be reported to ORO Central Office within five working days.
- Ensure that this VA facility obtains Full Accreditation of its HRPP by an Accrediting Organization under contract with VA unless this VA facility has a new IRB arrangement, in which case ensure that this VA facility or its academic affiliate’s IRB services:
  - Submits an application to the Accrediting Organization under contract with VA not more than 18 months after the first protocol is approved by the new IRB.
  - Obtain Full Accreditation within 18 months after the application submission date.
- Ensure that once this VA facility achieves Full Accreditation of its HRPP, it adheres to the Accrediting Organization’s requirements for maintaining accreditation.
- Report any change in the facility’s accreditation status in accordance.
- Provide an annual report to ORD and the Accrediting Organization under contract with VA. The annual report must be received by the deadline established by the Accrediting Organization. If this VA facility employs an academic affiliate IRB as one of its IRBs of Record, the annual report must include the current accreditation status of the academic affiliate.

When this VA Facility has its own IRB or serves as an IRB of record this VA facility Director is responsible to:

- Appoint the IRB Chair (or Co-Chairs, or Chair and Vice Chair), and IRB voting members.
  - If local Standard Operating Procedures (SOPs) call for titles of positions (e.g., Assistant Chief of Staff (ACOS) for R&D, Administrative Officer (AO) for R&D), instead of named individuals, to serve as ex officio, nonvoting members of the IRB, the individuals themselves do not have to be appointed by the IO. They will be considered to be ex officio, nonvoting members of the IRB by virtue of their positions within the local facility.
  - If this VA Facility’s own IRB serves as an IRB of record for a second VA facility, the facility Director of the second VA facility must appoint representatives to the first IRB.
• Suspend or terminate the IRB membership of any individuals who are not fulfilling their member responsibilities or obligations.
• Ensure an annual evaluation of the facility’s HRPP.

When this VA Facility uses an external IRB as an IRB of record this VA facility Director is responsible to:

• Sign the Memorandum of Understanding with the Organization providing the IRB. This Memorandum of Understanding is an agreement delineating the respective roles, responsibilities, and authorities of this VA Facility and the external organization providing the IRB, including, but not limited to, the external organization’s providing unredacted IRB minutes and other relevant documents to this VA Facility, and the responsibility for both parties to comply with all applicable VA and other Federal requirements.
• Ensure the external IRB of record complies with all applicable VA and other Federal requirements including, but not limited to, the provisions of this Handbook when reviewing VA research. If the terms of the Memorandum of Understanding are not met, this VA Facility must make alternative IRB arrangements.
• Appoint two or more VA-compensated employees who hold a minimum of 5/8th VA-compensated appointments as representatives to serve as voting members of each affiliate’s IRB or other local VA facility’s IRB when that IRB serves as an IRB of record, unless a waiver for such representation is obtained from the CRADO.
  o These representatives may not include WOCs from this VA Facility, or those with IPA appointments.
  o At least one of these representatives must have scientific expertise.
  o The representatives must serve as full-voting members of the external IRB; when relevant, this includes reviewing non-VA research matters coming before the IRB.
• At least one of the representatives must be present during the review of this VA Facility’s research at a convened IRB meeting.

When this VA Facility uses the VA Central IRB as an IRB of record this VA facility Director is responsible to:

• Sign and adhere to the Memorandum of Understanding between VHA Central Office and the local VA facility delineating the respective authorities, roles and responsibilities of each organization, include the VHA Central Office, the VA Central IRB, and the local VA facility when the local VA facility elects to use the VA Central IRB as an IRB of record.
  o A new Memorandum of Understanding must be executed when there is a change in the federalwide assurances (FWA) signing official (e.g., when there is a new facility Director or acting facility Director).
• Modifying the federalwide assurances (FWA) to list the VA Central IRB as an IRB of record.
• Maintaining SOPs for using the VA Central IRB as an IRB of record.
• Retaining responsibility for oversight of the local HRPP.
• Delegate authority to an individual from the local VA facility to:
Comment and Respond to VA Central IRB Review. In this instance, it is to:
- Provide comments or suggestions to VA Central IRB, in response to VA Central IRB’s initial review considerations; and
- Respond to VA Central IRB’s approval of the study on behalf of this VA facility as to whether this VA Facility chooses to participate or declines to participate in the study.

Serve as Liaison. In this instance, it is to serve as the liaison between the facility and both LSI and VA Central IRB.

When this VA Facility conducts international research the VA Facility Director is responsible to:
- Approve the request for permission to conduct international research prior to forwarding it to the CRADO for action.
- Ensure permission has been obtained from the CRADO, or designee, for the international research prior to its initiation by an investigator at the facility.

Veterans Administration (VA) Research Compliance Officer (RCO)

The Veterans Administration (VA) Research Compliance Officer (RCO) reports directly to the Veterans Administration (VA) Facility Director. Research compliance officer activities may not be determined or managed by the Research Service, research investigators, or any other research personnel. The IRB accept audits conducted by the research compliance officer to fulfill the IRB’s auditing requirements.

The Research Compliance Officer has the responsibility to:
- Audit and review research projects relative to requirements for the protection of human subjects including:
  - Annual consent document audits.
  - Triennial regulatory audits on all research protocols.
- Consider auditing research projects more frequently in cases of:
  - Involvement of vulnerable populations
  - Level of risk
  - Phase I or Phase II studies
  - Involvement of FDA approved drugs for which there has been a new safety warning issued, or change in the labeling that indicates increased risks
  - Issues of noncompliance
  - Data confidentiality or security concerns
- Within five business days of identifying apparent Serious Non-Compliance or Continuing Non-Compliance based on an consent document audit, regulatory audit, or other systematic audit of VA research, a research compliance officer must report the apparent non-compliance directly (without intermediaries) to the Facility Director.
  - The report must be made in writing, with a simultaneous copy to the associate chief of staff for research, the Research and Development Committee, the IRB, and any other relevant research review committee.
  - An initial report of apparent serious or continuing non-compliance based on a Research Compliance Officer consent document audit, Research Compliance
Human Research Protection Program Plan

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-101</td>
<td>01/01/2015</td>
<td>18 of 29</td>
</tr>
</tbody>
</table>

Officer regulatory audit, or other systematic Research Compliance Officer audit is required regardless of whether disposition of the matter has been resolved at the time of the report.

The Research Compliance Officer has the authority to:

- Serve as a nonvoting consultant, as needed, to the IRB.
  - The research compliance officer may not serve as a voting or nonvoting member of the IRB.
- Attend meetings of the IRB when requested by the IRB.

Veterans Administration (VA) Privacy Officer and the Information Security Officer

The Privacy Officer and the ISO are responsible to:

- Ensure the proposed research complies with all applicable local, VA and other Federal requirements for privacy and confidentiality, and for information security, respectively, by identifying, addressing, and mitigating potential concerns about proposed research studies, and by serving in an advisory capacity to the IRB or R&D Committee as a nonvoting member.
- Review the proposed study protocol and any other relevant materials submitted with the IRB application.
- Complete their respective reviews of the proposed research and informing IRB of all their findings related to privacy and confidentiality, and to information security, respectively.
- Identify deficiencies in their respective reviews of the proposed research, and making recommendations to the investigator of options available to correct the deficiencies.
- Follow up with the investigator, in a timely manner, to ensure the proposed research is in compliance with relevant privacy and confidentiality, and information security requirements, respectively, before the investigator initiates the study.
- Provide summary reports of their review and assessment of each study according to the requirements of this paragraph. The summary report must clearly:
  - Indicate either that all applicable local, VA and other Federal requirements for privacy and confidentiality, and for information security, respectively, have been met, or
  - Identify specific deficiencies and suggest available options for correcting those deficiencies.
- Provide their summary reports on each study to the IRB staff (whether VA or affiliate IRB) within a time frame that does not prolong the study approval process. They must provide their summary reports prior to, or at, the convened IRB meeting at which the study is to reviewed or, in the case of expedited review, prior to, the IRB approval determination of the IRB Chair, or designee. For exempt studies, they must submit their summary reports to the ACOS for R&D, and ensure the study is in compliance before the study is initiated.
- Provide their final reports on each study to the IRB staff (whether VA or affiliate IRB) in a timely manner.
All members of the Organization

All individuals within the Organization 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 Chancellor 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.
- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the HRRC.
- For Veterans Administration (VA) research follow this Organization’s procedures to ensure reporting in writing to the HRRC within 5 business days of becoming aware of unanticipated problems involving risks to subjects or others, apparent serious or continuing non-compliance, suspension of HRRC approval, termination of HRRC approval, and local (i.e., occurring in the reporting individual’s own VA facility) unanticipated serious adverse events in writing to the IRB within five business days of. This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA requirements.) The unfounded classification of a serious adverse event as “anticipated” constitutes serious non-compliance.

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 listed in the IRB rosters available from the Human Research Protections Office.

This Organization may rely upon IRBs of another organization with the approval of the Vice Chancellor for Research.


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 one of the IRBs designated by the Organizational Official. Officials of this Organization may not approve Human Research that has not been approved by one of the Organization’s IRBs.
Human Research Protection Program Plan

- 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.

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 observe 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.
Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the Institutional Official, HRCC, 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 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 Organization’s pharmacist shall conduct, participate in and support medical and pharmaceutical research appropriate to the goals, objectives and resources of the Organization.

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.

C. A copy of the research protocol for a study involving investigational drugs and the Organization's patients, shall be provided to the pharmacist. A copy of drug protocols
Institutional Biosafety Committee

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 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 not considered standard-of-care. 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;
(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.
Research and Development Committee (VA)

For Veterans Administration (VA) research, the Research and Development Committee has the responsibility for oversight of the local research program as defined in VHA Handbook 1200.01. The Veterans Administration (VA) Research and Development Committee has delegated its responsibility to conduct scientific review to the IRB.

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

HRRRC members, HRPO staff, and others involved in the review of Human Research must complete initial and continuing training.

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

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

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

Education and Training for Veterans Administration (VA) Research

All individuals involved in conducting VA human research are required to successfully complete training in ethical principles on which human research is to be conducted and accepted Good Clinical Practices. All other applicable VA and VHA training requirements at the local and national level must be met (e.g., privacy training).

Training provided by some VA facilities and by some VA facilities’ academic affiliates has been approved by ORD to meet the training requirement for Good Clinical Practices and the ethical principles on which human research should be conducted. For example, if investigators with dual appointments at the VA and those academic affiliates take the affiliates’ training in Good Clinical Practices and the ethical principles on which human research should be conducted, the investigators do not have to take the VA’s version of the same kind of training, but they must present documentation that they have completed this training to their VA Research Office. A list of approved alternative training sources is posted on the ORD Web site at http://www.research.va.gov/programs/pride/training/options.cfm. ORD will review other training upon request to determine whether or not it meets the requirements of this Handbook.
Human Research Protection Program Plan

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-101</td>
<td>01/01/2015</td>
<td>24</td>
</tr>
</tbody>
</table>

All individuals who are subject to these training requirements must:

- Complete training in Good Clinical Practices and the ethical principles on which human research is to be conducted before they may participate in human subjects research, and
- Update such training every 2 years thereafter. Local facilities have the option of defining “every 2 years” as within 730 days after the previous training, within the second full calendar year after the previous training, or within the second full fiscal year after the previous training. Each facility must specify which definition of "every 2 years" it uses in its policies and procedures for this training requirement.

This training requirement applies to all individuals involved in the conduct of VA human subjects research regardless of pay status, appointment type (title 38, title 5, IPA, or WOC), and length of time at this VA facility, including, but not limited to:

- Investigators;
- Study coordinators;
- Research assistants;
- Other members of the research team;
- Trainees, such as house officers and students;
- All members of the research office whose responsibilities include involvement with human research (e.g., the ACOS for R&D and the AO for R&D);
- All VA IRB staff, all VA IRB voting members, and all ex officio, nonvoting members of VA IRBs;
- VA representatives to external IRBs (e.g., affiliated academic institutions);
- All voting, and ex officio, nonvoting members of R&D Committees; and
- Members of other research committees or subcommittees that review research involving human subjects.

This training requirement also applies to investigators and research team members conducting studies involving human subjects that are exempt from IRB review, as well as those conducting human research for which the IRB has granted a waiver of informed consent or a waiver of documentation of informed consent. Nonscientist members (e.g., clergy, lawyers, community representatives, subject advocates) may require individualized training to ensure comprehension of their responsibilities as an IRB member. If a local facility provides such training, it needs to be included in its SOPs.

This training requirement does not apply to:

- Secretarial support staff;
- Research office staff whose responsibilities do not involve human research (e.g., those who deal only with research involving animals), or
- Community members of the IRB. However, community members of the IRB must complete specific training for IRB members as defined in the facilities’ SOPs.
- Facility Directors are not required to complete this training, but are required to complete the required Assurance training.
If the IRB of an affiliated academic institution or other external organization serves as the IRB of record for this VA facility, the external IRB members are to be encouraged to complete VA required human subjects protection training or its equivalent. The local VA facility is not required to track such training.

Members of a data monitoring committee for a VA research study are encouraged to complete VA required human subjects protection training or its equivalent. The local VA facility is not required to track such training.

Individuals outside VA (e.g., phlebotomists, x ray, and laboratory technicians) who are not VA employees (paid, WOC, or IPA), and whose work occurs exclusively outside this VA facility (e.g., at affiliated academic institution), must meet their own institutions’ requirements for training, but the local VA facility is not required to track such training.

All members of the research team for a VA research study must be VA employees (paid, WOC, or IPA). The only individuals outside VA who do not need a VA appointment or VA-specific training are those who perform a service for the research study in the course of their usual clinical duties.

Individuals who provide services for the research study in the course of their routine clinical duties (e.g., an x-ray technician who performs a chest x-ray, or clinical laboratory technician who performs a routine blood count), but have no other role or responsibility for the research study, are not required to complete VA human research protection training.

Treatment of Research-Related Injuries to Human Subjects at Veterans Administration (VA) Facilities

VA medical facilities must provide necessary medical treatment to a research subject injured as a result of participation in a research study approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. This does not apply to:

Treatment for injuries due to non-compliance by a subject with study procedures.

Research conducted for VA under a contract with an individual or a non-VA institution.

Care for VA research subjects under this Paragraph must be provided in VA medical facilities, except in the following situations:

- If VA facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required. Under these circumstances, VA facility Directors may contract for such care (38 CFR 17.85(b)(1)).
- If inpatient care must be provided to a non-Veteran under this paragraph, VA facility Directors may contract for such care.

The sponsor cannot bill the injured subject’s insurance company for the injury; however, the sponsor is responsible for reasonable and customary costs incurred for treatment of injury reasonably related to the subject’s participation in the study described in the scope of work except to the extent that:

- The injury is attributable to the negligence or willful misconduct of an indemnitee; or
- The injury is attributable to failure to administer the test article as required in the protocol or to otherwise substantially follow the protocol.
If a research subject needs treatment in a medical emergency in a non-VA facility for a condition covered by this paragraph, VA facility directors must provide reasonable reimbursement for the emergency treatment in a non-VA facility.

**Credentialing and Privileging for Research at Veterans Administration (VA) Facilities**

All VA research staff (clinical and non-clinical) conducting human research (exempt or non-exempt) must be credentialed and privileged (if applicable) as required by current local, VA, VHA, and ORD requirements. Research staff (including volunteers) may only perform those activities in a research study for which they have the relevant:

- **Credentials.** Each member of the research staff must be appropriately credentialed, except individuals providing secretarial support who should undergo the Human Resource Management (HRM) process for administrative personnel.

- **Privileges**
  - If the local facility where the research is to be performed requires privileging to perform a given duty (e.g., a procedure) in the clinical setting, the individual must be privileged at that facility to perform the duty before the individual can perform that duty in the research setting.
  - If the local VA facility requires privileging to perform a given procedure, it is not sufficient for only the supervisor of the person performing the research procedure to be privileged for that procedure. The person actually performing the research procedure must be privileged for the procedure.

- **Research Scope of Practice or Functional Statement.**
  - Except as specified below, each member of the research team must have a research scope of practice statement or functional statement that has been approved by the individual’s immediate supervisor and the ACOS for R&D, and that defines the duties the person is allowed to perform for research purposes.
  - A research scope of practice statement or functional statement must be developed for all research personnel (clinical and non-clinical) who are not privileged for all the duties the person is allowed to perform for research purposes.
  - The research scope of practice statement or functional statement must be consistent with the occupational category under which the individual was hired, and it must not include any duties for which the individual is not qualified.
  - Current scopes of practice for all non-privileged research personnel must be retained by the Research Office.
  - A duty (e.g., a procedure) cannot be added to a scope of practice statement or functional statement, unless the individual meets all criteria to perform the duty in the clinical setting (e.g., the individual must be privileged for a procedure if privileging is required for that procedure in the local clinical setting).
  - If research personnel are involved in more than one study, the research scope of practice statement or functional statement may be written to cover multiple studies (i.e., personnel do not need a research scope of practice statement for each protocol).
o If an employee’s clinical privileges, clinical scope of practice statement, or clinical functional statement includes all of the duties necessary for a specific research study (e.g., taking a medical history, drawing blood, performing a muscle biopsy, ordering and interpreting laboratory tests), a separate research scope of practice statement or functional statement does not need to be developed. However, if there are additional duties, these need to be included in the research scope of practice statement along with a copy of the clinical privileges, clinical scope of practice statement, or clinical functional statement.

- License, Registration, and Certification.
  o The employee must have all required licenses, registrations, or certifications to perform a given procedure, intervention, or other activity in the research setting and practice only within the scope allowed by such licenses, registrations, or certifications.

**Student and Other Trainee Research at Veterans Administration (VA) Facilities**

Only students and other trainees (including residents and fellows), including VA employees, from schools with an academic affiliation agreement consistent with current VHA policy, may serve as investigators within this VA facility, or use data, or human biological specimens that have been collected within VA for clinical, administrative, or research purposes. A waiver may be obtained from the CRADO under special circumstances.

A VA investigator sufficiently experienced in the area of the trainee’s research interest must serve as investigator or co-investigator and is responsible for oversight of the research and the trainee. The investigator or co-investigator is responsible for ensuring the trainee complies with all applicable local, VA and other Federal requirements.

In conducting the research, the trainee must comply with all VA and other Federal and local institutional requirements, including those related to research, information security, and privacy.

If the trainee does not complete all aspects of the research prior to leaving VA, the VA employee serving as the investigator or co-investigator must ensure the protocol is completed or terminated in an orderly fashion, and in accordance with all applicable local, VA, and other Federal requirements.

When the trainee leaves VA, the VA employee serving as the investigator or co-investigator is responsible for ensuring all research records are retained by VA.

**Questions and Additional Information for the HRRC**

The IRB Office wants your questions, information, and feedback.

Contact and location information for the Human Research Protections Office is:

Catherine Penick  
Interim HRPP Director, Executive Research Operations Officer  
University of New Mexico Health Science Center  
Reginald Heber Fitz Hall, B71
Human Research Protection Program Plan

Albuquerque, New Mexico  87131
Email: hrpo@salud.unm.edu

(505) 272-1129 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 Chancellor 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.

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.

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 Chancellor for Research or the HRPP Director, the Institutional Official has the authority to amend this plan as deemed necessary.

Approved:

[Signature]

Paul B. Roth, MD, MS
Chancellor for Health Sciences
CEO, UNM Health System
Dean, School of Medicine

February 1, 2015