

# **Faculty Handbook**

# **E110:** Conflict of Interest in Research

Approved By: Faculty Senate and UNM President

Last Updated: Draft 10/1/25

Responsible Faculty Committee: Research Policy Committee

Office Responsible for Administration: Vice President for Research and Health Sciences Vice

President for Research (HSVPR)

Legend: <u>Red</u> text is new wording, <u>strikeouts</u> show proposed deletions, Language that is shown in black (not underlined) reflects language that is in one of the current policies and is not proposed to change.

Revisions to the Applicability, Policy Rationale, and Policy Statement sections of this document must be approved by the full Faculty Senate and the UNM President.

## **APPLICABILITY**

This Policy applies to all investigators including non-UNM investigators who are responsible for the design, conduct, or reporting of University of New Mexico (UNM) research, including UNM faculty, staff, students, post-doctoral fellows, and volunteers, and non-UNM investigators who are not subject to their own institutional conflict of interest (COI) policy. The Policy covers actual and potential COI conflicts of interest associated with participation in UNM research, which includes:

- 1. Research funded by or through UNM (including outside sponsored funding);
- 2. Research conducted at UNM, regardless of funding; and
- 3. Non sponsored Unsponsored research conducted off campus by UNM employees.

## **B.** Disclosure Requirements

The conflict-of-interest disclosure requirements apply to all investigators who work on:

- 1. Sponsored UNM research.
- 2. Non sponsored UNM research that is:
  - a) Human subject research;
  - b) Animal subject research; or-
  - c) Research funded by a formal award from internal UNM sources based on submission of a proposal.

## **POLICY RATIONALE**

The purpose of this Policy is to protect the integrity, trust, and respect of UNM, its academic community and its research activities. This Policy is intended to enable compliance with applicable laws and other regulatory requirements and to protect investigators who may be exposed to conflict of interest (COI) including conflict of commitment (COC) situations when conducting research. It is designed to inform investigators of their disclosure responsibilities,

provide an efficient method for making disclosures, and facilitate effective identification and management of COIs or COCs. conflicts of interest.

## **POLICY STATEMENT**

Members of the UNM community are engaged in many contractual, consulting, and advisory relationships with other universities, government agencies and private sector entities. UNM encourages these relationships for their contributions to research, education, technological advancement, and professional development. UNM members must be cautious, however, to prevent unresolved COIs or COCs conflicts of interest in these relationships that might undermine the credibility of their work or damage their reputation. Additionally, full-time faculty members and researchers must be mindful of their obligation to devote their primary professional efforts and allegiance to UNM. Other activities should not interfere or significantly conflict with this responsibility. It is the intent of this Policy to provide assurance to investigators, UNM, sponsors of institutional research, and the public that research activities at UNM will be conducted in a manner consistent with institutional and public values.

### 1. Conflicts of Interest (COI)

Conflicts of interest COI or the appearance of COI may occur when an investigator's research responsibilities compete with his or her their private interests, such as financial interests, raising questions of objectivity and improper gain. Conflicts of interest COIs are inevitable in modern research universities and do not imply any impropriety on the part of the investigator. A conflict of interest COI may exist despite the highest standards of conduct and candor. Most conflicts can be successfully resolved without impeding research activities.

#### 2. Disclosure

Disclosing the required information at the earliest possible time will afford the best protection of an investigator's interests. Disclosure early in the UNM research is a key factor in protecting an investigator's reputation and career from potentially embarrassing or harmful allegations of inappropriate behavior. Investigators are encouraged required to disclose any situation that to the best of their knowledge could conceivably be viewed as a conflict of interest COI or a reportable financial interest, and to favor more rather than less disclosure. See the Definitions Section of this Policy for examples of situations that may require disclosure. The Conflicts of Interest Committee will assess whether an actual or potential conflict exists and work with the investigator to determine how it should be resolved or managed.- Individuals who are uncertain about this Policy's application to their situation should contact the Office of Research Integrity and Compliance (ORIC) or HSC Conflict of Interest and Commitment Office (collectively, UNM COI offices). Services (ORS) for assistance

#### 3. Training Requirements

Investigators must complete COI training as required by UNM COI Offices every four (4) years, unless funding agency and sponsor policies require more frequent training. When certain revisions to this Policy are made, when an investigator changes institution, or when an investigator is found to be out of compliance with this Policy, training will be required within sixty (60) days.

#### 4. Conflicts of Interest COI Committees

There will be one or more Conflicts of Interest COI committees formed at the Provost's and Executive Vice President for Health Sciences (EVPHS)'s discretion. The applicable Conflicts of Interest COI Committee will regularly review and assess conflict of interest COI disclosure forms referred to them by ORS or HSC SPO-a UNM COI Office to determine whether an actual or potential conflict exists and work with the investigator to determine how it might should be resolved or managed to best protect the investigator, the institution, and the research results.

An investigator may appeal the <u>COI</u> Committee decision to the Provost/<u>EVPHS</u> or designee, who will meet with the investigator and the <u>COI</u> Committee (or its representative) prior to making a final decision on the appeal. No research expenditures will be made <u>The investigator will not have</u> spending authority on research grants and contracts pending appeal.

#### 6. Confidentiality of Disclosures

All individuals involved in handling a disclosure should <u>must</u> exercise care at all times to protect the confidentiality of the disclosed information and the privacy of the investigator, to the extent permitted by law. <u>Individuals may be required to sign appropriate confidentiality</u> agreements, especially individuals external to UNM.

### 7. Applicability of Federal and State Rules

If a federal agency issues rules governing <u>COI</u> conflicts of interest in sponsored <u>UNM</u> research, those rules will govern where applicable. Proposals submitted for funding to the Public Health Service and the National Science Foundation are subject to specific legal requirements concerning financial conflicts of interest. This Policy is intended to comply with those requirements. Any changes in the federal requirements will supersede the relevant provisions of this Policy. New Mexico's Governmental Conduct Act, NMSA Section 10-16-3 (C) also has disclosure requirements pertaining to potential conflicts that must be followed in addition to the federal requirements.

Every investigator is <u>UNM COI offices</u> are responsible for being familiar with and following <u>updating the</u> <u>COI disclosure forms to follow</u> the provisions of governing laws and rules related to <u>COI.</u> conflicts of interest.

Revisions to the remaining sections of this document may be amended with the approval of the Faculty Senate Research Policy Committee, Policy Committee, and Operations Committee.

## **PROCEDURES**

#### 1. <u>Initial</u> Disclosure Procedures

#### 1.1 Sponsored Research Proposals: UNM Investigators

**1.1.1**. At the time When required by the funding agency, prior to submission of a sponsored research proposal is submitted to ORS to the Office of Sponsored Projects (OSP) or the Health

<u>Sciences Sponsored Project Office (HS-SPO)</u>, Health Sciences Center Pre-Award Administration Office (HSC-PAA) all UNM individuals who will serve as investigators on the proposed research must concurrently submit a completed conflict of interest <u>COI</u> form that discloses the following, among other things:

- a) Any significant financial interest that would reasonably appear to be affected by the research.
- b) Any significant financial interest in an entity whose financial interests would reasonably appear to be affected by the research.
- c) Any other situation that could call into question the investigator's professional commitments to UNM in undertaking the research. , or the investigator's primary allegiance to UNM.
- **1.1.2.** The principal investigator, and any co-principal investigator, are responsible for identifying the research investigators, informing them of the requirements of this Policy, and providing a list of their names to <a href="the COI Office">the COI Office</a>. ORS or HSC PAA. The COI Office ORS or HSC PAA should must receive completed disclosure forms from each investigator prior to the proposal's submission to the funding <a href="majoragency">agency</a>. Source. If the funding <a href="majoragency">agency</a> does not require a separate COI disclosure, the Annual COI Disclosure forms on file with a UNM COI Office will be deemed sufficient.
- 1.1.3. No research expenditures associated with the individuals that may have a potential COI will be allowed on a new/renewed award until disclosures have been reviewed and any conflicts have been properly managed. The same procedures apply for proposals submitted to ORS or HSC-PAA for renewal funding. Any new investigators must provide a completed conflict of interest form, and continuing investigators who provided a conflict of interest form with the original proposal must confirm or revise their form at the time of submission.

# 1.2. Sponsored Research Proposals: Non-UNM Investigators

For non-UNM investigators who will work on sponsored UNM research, the following conditions must be satisfied. when the proposal is submitted to ORS or HSC PAA:

- **1.2.1**. If the research will involve a sub-award with an entity that employs the non- UNM investigator, that entity must provide adequate <u>documentation</u> <u>assurances</u> to UNM that its system for compliance with federal <u>and state</u> <u>conflict of interest</u> <u>COI</u> requirements will address the proposed research. If the entity is unable to provide <u>this documentation</u> <u>these assurances</u> in a timely fashion, the non-UNM investigator must follow the disclosure requirements and procedures specified for UNM investigators. <u>These actions must be completed prior submission of the proposal.</u>
- **1.2.2.** All other If there is no sub-award, non-UNM investigators must follow the disclosure requirements and procedures specified for UNM investigators.
- 1.3. Non Unsponsored Research and UNM-Sponsored Research
- **1.3.1.** Each UNM investigator whose <u>unsponsored</u> UNM research <u>or UNM sponsored research</u> involves human subject research, animal subject research or research funded by a formal award from

internal UNM sources based on submission of a proposal must submit a completed conflict of interest COI disclosure form to the COI Office. ORS or HSC-PAA. The disclosure form must be submitted to the COI Office. ORS or HSC-PAA before the non unsponsored or UNM sponsored research proposal is submitted to the Institutional Review Board (IRB) human or animal subject research review committee or the Research Allocation Committee If a current or updated (see sections 2.1 and 2.2 below) Annual COI Disclosure is on file with UNM COI Offices, no additional disclosure is required.

- **1.3.2.** Investigators working on other types of non-sponsored UNM research are encouraged to voluntarily submit disclosure forms to ORS or HSC-PAA, as appropriate.
- **1.3.2.** UNM employees working on non unsponsored research at other institutions must submit a disclosure to UNM and provide the institution any applicable COI management plan. are encouraged for their self-protection to follow the COI procedures of their host institution.

## 2. Ongoing Disclosure Responsibility Procedures

- **2.1.** Disclosure requirements apply for the duration of the UNM research. Investigators must disclose any of the following, among other things, that occur during the sponsored conduct of UNM research:
  - a) A new significant financial interest that would reasonably appear to be affected by affect the research.
  - b) A new significant financial interest in an entity whose financial interests would reasonably appear to be affected by affect the research.
  - c) A new situation that could call into question the investigator's professional commitments in undertaking the research or the investigator's primary allegiance obligation to UNM.
  - d) A significant change to a previously reported disclosure.
- **2.2.** Investigators must submit updated disclosure forms to the COI Office ORS or HSC-PAA within thirty (30) days after the disclosable situation arises.
- **2.3.** All newly added investigators on UNM research must submit a completed conflict of interest COI disclosure form to the UNM COI Office ORS or HSC-PAA within thirty (30) days after from beginning work on the research. The principal investigator, and any co-principal investigator, are responsible for informing newly added investigators of this requirement and ensuring that they submit disclosure forms. Newly added investigators are subject to the ongoing disclosure requirements of this section.

#### 3. Conflicts of Interest UNM COI Offices and COI Committees

**3.2**. The UNM COI Office, in consultation with the relevant COI Committee Chair, may refer a disclosure to the COI Committee if the conflict has the potential to be categorized as high risk or otherwise requires COI Committee review.

#### 3.3. **COI Committee** Composition

- **3.3.1.** The membership of each COI committee will comprise six (6) faculty members, two (2) people one (1) person not primarily employed by UNM, and one (1) two (2) UNM officials with administrative responsibility for contracts. Notwithstanding the formation of two (2) or more COI committees, these conflict of interest COI committees will be referred to collectively as "the Conflict of Interest COI Committee" in all other sections of this Policy.
- **3.3.2.** Half of the Members of the COI Committee will be selected by the Provost or the EVPHS in consultation with the current Chair of the relevant COI Committee. in each category will be based on recommendation from the Vice Provost for Research. Members selected by the EVPHS in each category will be based on recommendation from the and half will be based on recommendation from the.
- **3.3.3.** Each <u>COI</u> Committee member will serve a three (3)-year, renewable term. The terms will be staggered to allow for continuity and rotation of members. Upon adoption of this <u>revised</u> Policy,-the members of the <u>Conflicts of Interest COI</u> Committees established under <u>previous UNM's</u> Policy-and Procedures on Conflicts of Interest in Sponsored Research (1992)-will continue to serve their appointed terms. as members of this Committee. The UNM official with administrative responsibility for contracts and grants may be assigned on the case-by-case basis, rather than serving the full term.
- **3.3.4.** Terms shall begin July 1 and will end on June 30, three (3) years later. If more than one (1) committee has been formed, the Provost/EVPHS will periodically switch some members among the committees in order to promote integration of viewpoint between the committees. The Provost/EVPHS may rearrange membership in this manner annually, at the time of formation of a new committee, or at other times as necessary to promote the goals of this paragraph. In the event of a vacancy, the replacement committee member will be appointed by the same method and from the same category as the departing member and shall serve for the remaining duration of the departing member's term.

#### 3.4. Decision Making

A quorum consisting of a simple majority of serving members of six (6) members is required for the COI Committee to perform its functions. Each member has one (1) vote and Decisions are to be made by majority vote. The Committee may develop guidelines for reviewing and assessing disclosures.- When more than one committee has been formed, any such guidelines must be approved by all committee members.

## 3.5. Disqualification Recusal of COI Committee Members

Under certain circumstances, <u>COI</u> Committee members may <u>have to recuse themselves</u> <del>be</del> <del>disqualified from reviewing a disclosure.</del> The standard for <del>disqualification recusal</del> is a reasonable belief that a member may be unable to make a decision based solely on the evidence. Examples of situations that would warrant <del>disqualification recusal</del> include:

- a) The member is directly involved in the disclosure under review.
- b) The member has a prior personal or professional relationship with the investigator that would interfere with the member's objectivity.
- c) The member's objectivity or ability to serve reasonably appears to be adversely affected by the circumstances.
- **3.5.1.** COI Committee members may self-recuse at any stage in the review process.
- **3.5.2.** An investigator may request recusal of a member at any stage in the review process. The <u>COI</u> Committee will deliberate and decide on this request in the absence of the member whose <u>disqualification recusal</u> is sought.
- **3.5.3.** If the Committee is unable to form a quorum Upon recusal of a member, the <u>COI</u> Committee <u>Chair, in consultation with the Provost/EVPHS</u>, will randomly select a former temporary member from the same category as the recused member to serve on the <u>COI</u> Committee on an interim basis for the remainder of the disclosure review and assessment.

## 3.6. Removal of **COI** Committee members

A member will be removed only for good cause and only by the Provost/EVPHS upon recommendation of a majority of a quorum of the <u>COI</u> Committee on which the member sat. Good cause will include:

- a) Change in eligibility status.
- b) Insufficient attendance at COI committee meetings.

## 4. Review and Management of COI Disclosures

#### 4.1. Initial Screening

- **4.1.1.** The UNM COI Offices will be responsible for initial screening of COI disclosure forms. The UNM COI Office, in consultation with the applicable COI Committee Chair, will review all disclosure forms and refer those that indicate a possible conflict of interest COI to the applicable Conflicts of Interest COI Committee, unless otherwise specified in any screening guidelines provided by the COI Committee. In addition, if the research involves human or animal subjects, or research funded by a formal award from internal UNM sources based on submission of a proposal, the UNM COI Office ORS or HSC PAA will notify the Institutional Review Board (IRB) or the Research Allocation Committee (RAC) that send copies of disclosure forms that indicate conflict of interest a possible conflict of interest COI exists. to the human or animal subject research review committee or the Research Allocation Committee, as appropriate.
- **4.1.2.** If the referred disclosure form was submitted by an investigator other than the principal investigator, the <u>UNM COI Office ORS or HSC PAA</u> will notify the principal investigator of the general nature of the referral without divulging the particulars of the disclosed information.

## 4.2. Determination of **COI** Conflicts of Interest

- **4.2.1.** The <u>Conflicts of Interest COI</u> Committees will regularly review and assess <u>conflict of interest COI</u> disclosure forms referred by <u>the UNM COI Offices-ORS or HSC-PAA</u>. If the <u>COI</u> Committee determines after initial review of a disclosure that no <u>conflict of interest COI</u> exists, it will conclude its assessment. If the <u>COI</u> Committee is unable to make this determination, it <u>will may</u> invite the investigator who submitted the disclosure to meet with the <u>COI</u> Committee, <u>COI Committee</u> <u>Chair, or designee</u> and explain the circumstances of the UNM research and the possible <u>COI conflict of interest</u>. The <u>COI</u> Committee will determine whether a <u>COI conflict of interest</u> exists, and if so, work with the investigator to determine how it might be managed or resolved to best protect the investigator, the institution and the research results.
- **4.2.2.** On occasion, circumstances may require the Provost/<u>EVPHS</u> or designee to make an expedited decision to accept funding for UNM research before the <u>COI</u> conflict of interest Committee has had an opportunity to review a disclosure related to the research. In that event, the <u>COI</u> Committee subsequently will review and assess the disclosure according to its regular process. No research expenditures <u>associated with the individuals that may have a potential COI</u> will be made pending <u>COI</u> Committee review <u>or resolution of the conflict</u>.

#### 4.3. Role of Principal Investigator

- **4.3.1.** When the investigator whose disclosure is reviewed by the conflict of interest COI Committee is not the principal investigator for the UNM research, the privacy of the investigator must be balanced with the principal investigator's need for sufficient information to manage the research responsibly. Accordingly, if the COI Committee believes upon initial review of the disclosure that a conflict of interest COI may exist, the COI Committee will ask the investigator for consent to reveal the disclosure to the principal investigator and to invite the principal investigator to meet with the COI Committee and participate in discussion of the research circumstances.
- **4.3.2.** If the investigator consents to the principal investigator's participation, the <u>COI</u> Committee will proceed accordingly. If the investigator refuses consent, the <u>COI</u> Committee will keep the disclosure details confidential and proceed in its assessment of the disclosure with the investigator's participation. Despite the refusal, the <u>COI</u> Committee may confer generally with the principal investigator about the research and the investigator's role in it, revealing no more than the overall nature of the possible conflict.
- **4.3.3.** If the <u>COI</u> Committee finds that an investigator who did not consent to the principal investigator's participation in the review process has a <u>COI</u> conflict of interest, the <u>COI</u> Committee will try to manage the conflict in a manner that does not involve the principal investigator. The principal investigator should be involved in the conflict management plan only if the plan would affect the conduct of the research. Without the involvement of the principal investigator, the <u>COI</u> Committee cannot remedy the conflict by recommending modification of the research protocol or oversight of the research. Consequently, refusal to involve the principal investigator may prevent the effective management of a conflict. If the investigator and the <u>COI</u> Committee cannot agree on a resolution that would not affect the research, the investigator must either consent to involvement of the principal investigator in managing the conflict or withdraw from the research.

## 4.4. Management of **COI** Conflicts of Interest

- **4.4.1.** If the Conflicts of Interest COI Committee determines that an investigator has a conflict of interest COI in UNM research, it will decide how the conflict should be managed so the research may proceed if at all possible. The COI Committee may impose conditions or restrictions to control, reduce or eliminate the possibility that the conflict will affect the objectivity of the research. The COI Committee may designate other UNM officials to assist in this process. Examples of conflict-of-interest management options include, but are not limited to:
  - a) Public Disclosure of the conflict in publications and professional presentations.
  - b) Monitoring of the research by independent <u>experts familiar with the research subject,</u> <u>appointed by the COI Committee.</u> <u>reviewers.</u>
  - c) Modification of the research plan.
  - <u>d) Disclosure of the conflict to human research participants through an informed consent</u> document;
  - e) Request for an additional faculty advisor to monitor academic process of students involved in a researcher's commercial enterprise;
  - f) Divestiture of the investigator's conflicting financial interests or placement in a blind trust.
  - g) Escrow of an equity interest until certain triggering conditions are met.
  - h) Prohibition on the investigator's involvement in contract negotiations for the research.
  - i) Severance of the investigator's relationships that create the conflict.
  - j) Disqualification Withdrawal of the investigator from participation in part of the research.
- **4.4.2.** All Any conflicts of interest COIs must be resolved in accordance with a managed management plan approved by to the satisfaction of the COI Committee or the COI Committee Chair for the UNM research associated with the individuals that may have a potential COI to proceed. and for funding, if any, to be accepted. This applies to all UNM research that is subject to the disclosure requirements of this Policy, regardless of whether the research is funded. No conflicts may be waived. If a conflict of interest COI cannot be managed, the investigator must withdraw from the research and or UNM may need to decline acceptance of the award or terminate the sponsored agreement.

#### 4.5. Notification of **COI** Committee Decisions

- **4.5.1.** If the Conflicts of Interest Committee COI Committee determines that an investigator's disclosure does not constitute a COI conflict of interest, the Committee UNM COI Office will provide written notification of it's the decision and rationale to the investigator. the principal investigator if different from the investigator, the chair of the investigator's department, and the director of the center, if appropriate.
- **4.5.2.** If the <u>COI</u> Committee finds that a <del>conflict of interest</del> <u>COI</u> does exist, the <del>Committee</del> <u>UNM COI</u> <u>Office</u> will notify the same individuals, with the addition of the <u>investigator</u>, the <u>principal investigator</u> if <u>different from the investigator</u>, the chair of the investigator's department, the director of the

<u>center, if</u> appropriate, <u>the</u> dean, <u>and the supervisor if the investigator is not a faculty member,</u> of the existence of the conflict and the management plan.

- **4.5.3**. The <u>COI</u> Committee will provide copies of all of its decisions to the Provost/<u>EVPHS</u> and to either the <u>Associate Provost Vice President</u> for Research or the <u>HSC Vice President for Research</u> <u>Vice President for Health Sciences.</u>
- **4.5.4.** If the research involves human or animal-subjects, or research funded by a formal award from internal UNM sources based on submission of a proposal, the UNM COI Office ORS or HSC-PAA-will send copies of disclosure forms-notify the appropriate COI Committee that a management plan has been developed and approved. to the human or animal subject research review committee or the Research Allocation Committee, as appropriate.

#### 5. Appeals

An investigator may appeal the <u>COI</u> Committee decision in accordance Section 5 of the Policy Statement above. <u>to the Provost or designee, who will meet with the investigator and the Committee (or its representative) prior to making a final decision on the appeal.</u>

## 6. Reporting and Records Requirements

#### **6.1. Reports to Research Sponsors**

The <u>UNM COI Offices</u> Conflicts of Interest Committee, <u>OSP and HS-SPO</u> ORS or HSC-PAA will work to ensure that UNM complies with the research sponsor's requirements for reporting <u>COIs.</u> conflicts of interest. As of the date of enactment of this policy, for example, UNM must inform the Public Health Service, prior to the expenditure of research funds, of the existence of any actual conflicts of interest in the funded research and provide assurances of their management in accordance with federal requirements. UNM also must report and handle subsequently arising conflicts in PHS funded research within sixty (60) days after their identification. UNM is required to report to the National Science Foundation only conflicts of interests that have not been managed prior to expenditure of award funds, and keep the agency informed if a conflict cannot be managed successfully.

#### 6.2. Records Retention

ORS The UNM COI Offices will keep records of all conflict of interest COI disclosures and all actions taken with respect to those disclosures for at least three (3) years after the later of these events:

- Termination or completion (the date the final expenditures report is submitted) of the UNM research;
- Resolution of any government action involving the records; or
- As otherwise provided by law.

#### 7. Policy Enforcement

## 7.1. Types of Noncompliance

Noncompliance with this Policy can occur through the following actions:

- Failure to disclose required information, or
- Failure to follow a conflict-of-interest management plan.

#### 7.2. Enforcement Responsibility

The Provost/<u>EVPHS</u> or designee is responsible for enforcing this Policy, including investigating and sanctioning noncompliance. The <u>Conflicts of Interest COI</u> Committees <u>are</u> is responsible for reviewing <u>the cases referred to it them</u> and <u>managing conflicts of interest referred to it during an enforcement process</u>. The Provost/<u>EVPHS</u> or designee may consult with the <u>COI</u> Committee during this process.

## 7.3. Reporting Noncompliance

- **7.3.1.** Anyone who suspects that an investigator has not complied with this Policy may bring the matter to the attention of the principal investigator, if different from the investigator. If this is not feasible or does not resolve the matter, individuals should report their concerns to the Provost/<u>EVPHS</u> or designee. The <u>COI</u> Committee may likewise report its own concerns about an investigator's noncompliance.
- **7.3.2.** UNM encourages good faith reporting of conflict of interest COI concerns. UNM prohibits retaliation against a person who reports under this Policy in good faith. Retaliation for good faith reporting may result in disciplinary action up to and including dismissal. Similarly, UNM does not tolerate bad faith reporting. Reporting an individual in bad faith may result in disciplinary action up to and including dismissal.

## 7.4. Investigation

- **7.4.1.** The Provost/<u>EVPHS</u> or designee will investigate allegations of policy noncompliance. The procedures in <u>Faculty Handbook Policy</u> **C07** "Faculty Disciplinary Policy" and **E40** "Research Misconduct" UNM's Research Fraud Policy may be used for guidance. although investigations under this Policy may be handled less formally than specified in the Research Fraud Policy.
- **7.4.2.** Any information that arises from the investigation that is disclosable under Section <u>1</u> of these Procedures above 

  will be referred to the Conflicts of Interest COI Committee for review and management.

#### 7.5. Sanctions

The Provost/<u>EVPHS</u> or designee may employ a range of options and sanctions in handling investigator noncompliance, including disciplinary and legal action and refusing or rescinding acceptance of an award. If sanctions involve <u>UNM faculty, staff, or students, UNM discipline policies must be followed.</u>

## 7.6 Notification of Research Sponsors

If an investigator's noncompliance with this Policy may have biased the design, conduct, or reporting of the UNM research, UNM will promptly notify the funding agency. Research sponsors may impose additional restrictions, including suspension of funding. For example, if

clinical research funded by the Public Health Service on the safety or efficacy of a drug, medical device or treatment was designed, conducted, or reported by an investigator with an undisclosed or unmanaged conflict of interest, the investigator will be required to disclose the conflict in each public presentation of the research results.

#### X. EFFECTIVE DATE

This policy will become effective three months after approval by the UNM Board of Regents.

## **DEFINITIONS**

**Conflict of Interest (COI)** is means a situation associated with an investigator's participation in UNM research where it reasonably appears, on an actual or potential basis, that the following circumstances may occur:

- a) **Financial COI**: The investigator <u>or the investigator's spouse, partner, or dependent children, has a significant financial interest <u>or financial relationship that</u> could directly and significantly affect the design, conduct, or reporting of UNM research <u>activity</u> activities; or</u>
- b) Conflict of Commitment (COC): a situation where an individual engages in outside research activities, either paid or unpaid, that interferes with or is similar to the individual's professional obligation and commitment to UNM. The investigator's situation could directly and significantly compromise their his or her professional commitments or allegiance to UNM.

Examples of the types of situations that may come within this definition include <u>but are not</u> limited to:

- a) Holding a direct or indirect interest in an outside entity that conducts business in an area closely related to the UNM research or serving as a director, officer, partner, trustee, manager, or employee in such an entity.
- b) Undertaking or steering UNM research to serve the research or other needs of an outside entity, without approval of UNM or and the research sponsor.
- c) Directing potential research efforts away from UNM and toward the investigator's outside entity, or an outside entity in which the investigator has a financial interest.
- d) Transmitting to an outside entity without <u>UNM and</u> the <u>research</u> sponsor's consent, or otherwise using for personal gain, sponsored work products, results, materials, records or information that are not generally made available. This does not necessarily preclude contracts between faculty start-ups and either UNM or <u>UNM Rainforest Innovations</u> (<u>UNMRI</u>) the Science & Technology Corporation @ UNM, although these contracts may give rise to <u>COI</u> conflict of interest situations.
- e) Using privileged information acquired in connection with the investigator's sponsored UNM research activities for personal gain or for unauthorized purposes. Privileged information includes medical, personnel or security records of individuals, anticipated

material requirements or price actions, possible new sites for government operations, and knowledge of forthcoming programs or selection of contractors or subcontractors in advance of official announcements.

- f) Negotiating or influencing the negotiation of contracts related to the investigator's sponsored UNM research between UNM and outside entities with which the investigator has consulting, equity, or fiduciary relationships.
- g) Accepting gratuities, <u>in-kind support</u>, or special favors from entities with which UNM does or may conduct business in connection with <del>sponsored</del> UNM research or extending gratuities or special favors to employees of the sponsor, under circumstances that reasonably might be interpreted as an attempt to influence the recipients in the conduct of their duties.
- h) Assignment of students or other supervisees into activities from which the employee intends to realize personal financial gain and/or that would compromise or interfere with the students' primary educational and research duties; and
- i) Accepting an honorary faculty position at a foreign institution.

<u>Conflict Management</u> comprises measures taken to address the risk of bias or the appearance of bias, protect research subjects, and maintain public trust in UNM research and its personnel when there may be a real or perceived COI. If the conflict can be managed, the COI Management Plan should be set forth in writing.

**Investigator** means the principal investigator, the co-principal investigator and any other person (including faculty, staff and students) <u>paid or unpaid</u> who is responsible for the design, conduct, or reporting of UNM research. Any individual responsible for a task that could have a significant effect on the research design, conduct, or reporting is considered to be an investigator, even if the individual does not have sole or primary responsibility for the task or the research.

#### **Non-UNM Investigator** means any person who is:

- 1. Responsible for the design, conduct, or reporting of UNM research; and
- 2. Employed by an entity other than UNM, working pursuant to a sub-award with another entity, working as an independent contractor or collaborator, or otherwise not employed by UNM.

Reporting of Research includes the authorship of publications to journals or otherwise, generating and submitting reports to a research sponsor, presentation at conferences or technical meetings related to the research, other public presentations, or research funding proposals.

**Significant Financial Interest (SFI)** means anything of monetary value belonging to the investigator and their his or her spouse or partner, or domestic partner and dependent children, including but not limited to:

- a) Salary, royalties or other payments for services, such as consulting fees or honoraria, unless they are expected to total \$10,000 or less totaling \$5,000 or more from a single entity over the next twelve (12) months preceding disclosure when aggregated for the investigator and their his or her spouse, partner, and dependent children.
- b) Equity interests, such as stocks, stock options or other ownership interests <u>amounting to</u> \$5,000 or more in value for publicly traded companies in a single entity when aggregated for the investigator and <u>their</u> his or her spouse, <u>partner</u>, and dependent children. <del>unless they amount to \$10,000 or less in value and represent a five percent (5%) or less ownership interest in a single entity when aggregated for the investigator and their spouse and dependent children.</del>
- c) <u>Royalties from</u> intellectual property rights, such as patents and copyrights, <u>and not</u> associated with UNM. royalties from these rights.

Significant financial interest SFI does not include the following:

- a) Salary, royalties or other remuneration from UNM including payments or other technology commercialization proceeds through the <u>UNMRI</u> the Science & Technology Corporation @ UNM (see **FH Policy E70** "Intellectual Property Policy").
- b) Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels for public or nonprofit entities a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- c) Interests in widely held investment funds vehicles, such as mutual funds and retirement accounts, if:
  - (1) The investigator does not exercise control over or have the ability to exercise control over the fund's financial interests; and
  - (2) Either
  - (a) The fund is publicly traded or available, or
  - (b) Its assets are widely diversified; for example, if the fund holds no more than 5% of its portfolio value in the securities of anyone issuer, other than the federal government, and no more than 20% of its portfolio value in any particular economic or geographic sector, or
  - (c) Interests <u>are</u> in blind trusts <u>and</u> if the investigator has no knowledge of the trust assets.

**UNM research** means a systematic investigation designed to develop or contribute to generalizable knowledge, including basic and applied investigations and product development, that is:

- 1. Funded by or through UNM (including outside sponsored funding);
- 2. Conducted at UNM, regardless of funding; or

3. Non sponsored and Unsponsored research conducted off campus by UNM employees regardless of where research is performed.

## WHO SHOULD READ THIS POLICY

- Faculty, staff, and students conducting research.
- Members of the Faculty Senate and the Research Policy Committee.
- Academic deans or other executives, department chairs, directors, and managers.
- Administrative staff responsible for research management.

## **RELATED DOCUMENTS**

## UNM Regents' Policy Manual

Policy 5.1 "The Faculty's Role in UNM's Academic Mission"

Policy 5.8 "Intellectual Property"

Policy 5.10 "Conflicts of Interest in Research"

Policy 5.13 "Research Fraud"

Policy 5.14 "Human Beings as Subjects in Research"

Policy 5.17 "Conflict of Interest Waiver Policy for Technology Transfer"

Policy 6.4 "Employee Code of Conduct and Conflicts of Interest Policy"

## Faculty Handbook

Policy C130 "Outside Employment and Conflicts of Commitment"

Policy E40 "Research Misconduct"

Policy E70 "Intellectual Property Policy"

Policy E80 "Conflict of Interest Waiver Policy for Technology Transfer"

Policy E90 "Human Beings as Subjects in Research"

University Administrative Policies and Procedures Manual

Policy 3720 "Employee Code of Conduct and Conflicts of Interest"

#### **Federal Regulations**

- 42 CFR Part 50
- 45 CFR Part 94
- 2 CFR 200.112
- PAPPG
- 34 CFR 75
- FAL Letter 2022-02

## CONTACTS

Direct any questions about this policy to Office of the Vice President for Research (VPR) or the HSC Vice President for Research (HSVPR).

## DRAFT HISTORY

October 1, 2025 – approved by Faculty Senate Policy Committee to go out for comment.

September 29, 2025 – revised by meeting with member of E110 subgroup and OVPR's office to review and resolve remaining items.

September 24, 2025 -- revised by E110 subgroup to address concerns raised.

September 18, 2025 – revised by E110 subgroup to address concerns raised.

January 13, 2025 – Revised for RPC changes

March 17, 2023—Draft prepared to place in new policy format and update titles.

## HISTORY

September 7, 2022 - Updated to reflect title changes for Vice President of Research, HSC Sponsored Projects Office, and Executive Vice President for Health Sciences, per FHB Policy A53 procedures

February 23, 2022 – Updated to reflect name change of the Science and Technology Corporation @ UNM (STC.UNM) to UNM Rainforest Innovations (UNMRI), per FHB Policy A53 procedures

May 12, 2003 – Approved by the President

April 22, 2003 – Revised by the Faculty Senate

April 11, 2000 – Adopted by the Board of Regents