

# CONFLICTS OF INTEREST IN RESEARCH

## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	APPLICABILITY	
	A. Overall Policy.....	2
	B. Disclosure Requirements.....	2
III.	DEFINITIONS	
	A. Conflict of Interest .....	2
	B. Investigator.....	3
	C. Non-UNM Investigator.....	3
	D. Significant Financial Interest .....	4
	E. UNM Research.....	5
IV.	CONFLICTS OF INTEREST COMMITTEE	
	A. Purpose.....	5
	B. Composition.....	5
	C. Decision Making.....	6
	D. Disqualification of Committee Members.....	6
	E. Removal of Committee Members.....	6
V.	DISCLOSURE REQUIREMENTS	
	A. General.....	7
	B. Sponsored Research Proposals: UNM Investigators.....	7
	C. Sponsored Research Proposals: Non-UNM Investigators .....	8
	D. Nonsponsored Research.....	8
	E. Ongoing Disclosure Responsibility.....	8
	F. Confidentiality of Disclosures.....	9
VI.	REVIEW AND MANAGEMENT OF CONFLICT OF INTEREST DISCLOSURES	
	A. Initial Screening .....	9
	B. Determination of Conflicts of Interest .....	10
	C. Role of Principal Investigator .....	10
	D. Management of Conflicts of Interest.....	11
	E. Notification of Committee Decisions.....	12
	F. Appeals .....	12
VII.	REPORTING AND RECORDS REQUIREMENTS	
	A. Reports to Research Sponsors.....	12
	B. Records Retention.....	12

VIII.	POLICY ENFORCEMENT	
A.	Types of Noncompliance .....	13
B.	Enforcement Responsibility.....	13
C.	Reporting Noncompliance.....	13
D.	Investigation.....	13
E.	Sanctions .....	14
F.	Notification of Research Sponsors.....	14
IX.	APPLICABILITY OF FEDERAL RULES .....	14
X.	EFFECTIVE DATE.....	14

## **CONFLICTS OF INTEREST IN RESEARCH**

### **I. INTRODUCTION**

The purpose of this policy is to protect the integrity, trust and respect of UNM, its academic community and its research activities. The 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 situations. It is designed to inform investigators of their disclosure responsibilities, provide an efficient method for making disclosures, and facilitate effective identification and management of conflicts of interest.

Members of the University of New Mexico 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 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.

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

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 to disclose any situation that could conceivably be viewed as a conflict of interest or a reportable financial interest, and to favor more rather than less 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 the policy's application to their situation should contact the Office of Research Services (ORS) for assistance.

## II. **APPLICABILITY**

### A. Overall Policy

This policy applies to all investigators, including non-UNM investigators. The policy covers actual and potential 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.
3. Nonsponsored 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. Nonsponsored 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.

## III. **DEFINITIONS**

### A. Conflict of Interest

1. Conflict of interest means a situation associated with an investigator's participation in UNM research where it reasonably appears, on an actual or potential basis, that:
  - a) The investigator's significant financial interest could directly and significantly affect the design, conduct or reporting of UNM research activities; or
  - b) The investigator's situation could directly and significantly compromise his or her professional commitments or allegiance to UNM.
2. Examples of the types of situations that may come within this definition include:

- 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 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 the 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 the Science & Technology Corporation @ UNM, although these contracts may give rise to 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 or special favors from entities with which UNM does or may conduct business in connection with sponsored 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.
- B. Investigator means the principal investigator, the co-principal investigator and any other person (including faculty, staff and students) 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.
- C. 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.

D. Significant Financial Interest

1. Significant financial interest means anything of monetary value belonging to the investigator and his or her spouse 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 over the next 12 months when aggregated for the investigator and his or her spouse and dependent children.
- b) Equity interests, such as stocks, stock options or other ownership interests, unless they amount to \$10,000 or less in value and represent a 5% or less ownership interest in a single entity when aggregated for the investigator and his or her spouse and dependent children.
- c) Intellectual property rights, such as patents and copyrights, and royalties from these rights.

2. Significant financial interest does not include the following:

- a) Salary, royalties or other remuneration from UNM (including payments or other technology commercialization proceeds through the Science & Technology Corporation @ UNM).
- b) Income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities.
- c) Income from service on advisory committees or review panels for public or nonprofit entities.
- d) Interests in widely held investment funds 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 any one issuer, other than the federal government, and no more than 20% of its portfolio value in any particular economic or geographic sector.
- e) Interests in blind trusts if the investigator has no knowledge of the trust assets.

- E. 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;
  - 3. Nonsponsored and conducted off campus by UNM employees.

#### IV. **CONFLICTS OF INTEREST COMMITTEE**

##### A. Purpose

- 1. The purpose of the Conflicts of Interest Committee is to protect the integrity of investigators, UNM, and UNM research by identifying and resolving conflicts of interest when they exist. The Committee carries out this charge in a manner that is intended to foster, not hinder, research relationships.
- 2. In addition to reviewing conflict of interest disclosures, the Committee may offer advice on general questions concerning conflicts of interest.

##### B. Composition

- 1. There will be one or more Conflicts of Interest Committees formed at the Provost's discretion. The membership of each committee will comprise six faculty members, two people not primarily employed by UNM, and two UNM officials with administrative responsibility for contracts. Notwithstanding the formation of two or more committees, these conflict of interest committees will be referred to collectively as "the Conflict of Interest Committee" in all other sections of this Policy.

Half of the members selected by the Provost in each category will be based on recommendation from the Vice President for Health Sciences, and half will be based on recommendation from the Vice Provost for Research.

- 2. Each Committee member will serve a three-year, renewable term. The terms will be staggered to allow for continuity and rotation of members. Upon adoption of this policy, the members of the Conflicts of Interest Committees established under UNM's Policy and Procedures on Conflicts of Interest in Sponsored Research (1992) will continue to serve their appointed terms as members of this Committee.

Terms shall begin July 1 and will end on June 30, three years later. If more than one committee has been formed, the Provost will periodically switch some members among the committees in order to promote integration of viewpoint between the committees. The Provost 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.

C. Decision Making

A quorum of six members is required for the Committee to perform its functions. Each member has one 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.

D. Disqualification of Committee Members

1. Under certain circumstances, Committee members may be disqualified from reviewing a disclosure. The standard for disqualification 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 disqualification include:
  - a) The member is directly involved in the disclosure under review.
  - b) The member has a prior 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.

E. Removal of Committee members

1. A member will be removed only for good cause and only by the Provost upon recommendation of a majority of a quorum of the committee on which the member sat. Good cause will include:
  - a) Change in eligibility status
  - b) Insufficient attendance at committee meeting
2. Committee members may self-recuse at any stage in the review process.

3. An investigator may request recusal of a member at any stage in the review process. The Committee will deliberate and decide on this request in the absence of the member whose disqualification is sought.
4. If the Committee is unable to form a quorum upon recusal of a member, the Committee will randomly select a former member to serve on the Committee on an interim basis for the remainder of the disclosure review and assessment.

## V. **DISCLOSURE REQUIREMENTS**

### A. General

The disclosure requirements of this policy apply to all UNM investigators working on:

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

### B. Sponsored Research Proposals: UNM Investigators

1. At the time a sponsored research proposal is submitted to ORS or the 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 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 in undertaking the research or the investigator's primary allegiance to UNM.
2. The principal investigator, and any co-principal investigator, are responsible for identifying the research investigators, informing them of the requirements of the policy, and providing a list of their names to ORS or HSC-PAA. ORS or HSC-PAA should receive completed disclosure

forms from each investigator prior to the proposal's submission to the funding source.

3. 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.

C. 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. If the research will involve a sub-award with an entity that employs the non-UNM investigator, that entity must provide adequate assurances to UNM that its system for compliance with federal conflict of interest requirements will address the proposed research. If the entity is unable to provide these assurances in a timely fashion, the non-UNM investigator must follow the disclosure requirements and procedures specified for UNM investigators.
2. All other non-UNM investigators must follow the disclosure requirements and procedures specified for UNM investigators.

D. Nonsponsored Research

1. Each UNM investigator whose UNM research 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 disclosure form to ORS or HSC-PAA. The disclosure form must be submitted to ORS or HSC-PAA before the nonsponsored proposal is submitted to the human or animal subject research review committee or the Research Allocation Committee.
2. Investigators working on other types of nonsponsored UNM research are encouraged to voluntarily submit disclosure forms to ORS or HSC-PAA, as appropriate.
3. UNM employees working on nonsponsored research at other institutions are encouraged for their self-protection to follow the conflicts of interest procedures of their host institution.

E. Ongoing Disclosure Responsibility

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 UNM research:
  - a) A new significant financial interest that would reasonably appear to be affected by the research.
  - b) A new significant financial interest in an entity whose financial interests would reasonably appear to be affected by 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 to UNM.
  - d) A significant change to a previously reported disclosure.
2. Investigators must submit updated disclosure forms to ORS or HSC-PAA within 30 days after the disclosable situation arises.
3. All newly-added investigators on UNM research must submit a completed conflict of interest disclosure form to ORS or HSC-PAA within 30 days after 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.

F. Confidentiality of Disclosures

All individuals involved in handling a disclosure should 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.

VI. **REVIEW AND MANAGEMENT OF CONFLICT OF INTEREST DISCLOSURES**

A. Initial Screening

1. ORS or HSC-PAA is responsible for initial screening of conflict of interest disclosure forms. ORS or HSC-PAA will refer all disclosure forms that indicate a possible conflict of interest to the Conflicts of Interest Committee, unless otherwise specified in any screening guidelines provided by the 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, ORS or HSC-PAA will send copies of disclosure forms that indicate a possible conflict of interest to the human or animal subject research review committee or the Research Allocation Committee, as appropriate.

2. If the referred disclosure form was submitted by an investigator other than the principal investigator, ORS or HSC-PAA will notify the principal investigator of the general nature of the referral without divulging the particulars of the disclosed information.

B. Determination of Conflicts of Interest

1. The Conflicts of Interest Committee will regularly review and assess conflict of interest disclosure forms referred by ORS or HSC-PAA. If the Committee determines after initial review of a disclosure that no conflict of interest exists, it will conclude its assessment. If the Committee is unable to make this determination, it will invite the investigator who submitted the disclosure to meet with the Committee and explain the circumstances of the UNM research and the possible conflict of interest. The Committee will determine whether a conflict of interest 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.
2. On occasion, circumstances may require the Provost or designee to make an expedited decision to accept funding for UNM research before the Conflicts of Interest Committee has had an opportunity to review a disclosure related to the research. In that event, the Committee subsequently will review and assess the disclosure according to its regular process. No research expenditures will be made pending Committee review.

C. Role of Principal Investigator

1. When the investigator whose disclosure is reviewed by the Conflicts of Interest 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 Committee believes upon initial review of the disclosure that a conflict of interest may exist, the 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 Committee and participate in discussion of the research circumstances.
2. If the investigator consents to the principal investigator's participation, the Committee will proceed accordingly. If the investigator refuses consent, the Committee will keep the disclosure details confidential and proceed in its assessment of the disclosure with the investigator's participation. Despite the refusal, the 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.

3. If the Committee finds that an investigator who did not consent to the principal investigator's participation in the review process has a conflict of interest, the 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 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 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.

D. Management of Conflicts of Interest

1. If the Conflicts of Interest Committee determines that an investigator has a conflict of interest in UNM research, it will decide how the conflict should be managed so the research may proceed if at all possible. The Committee may impose conditions or restrictions to control, reduce or eliminate the possibility that the conflict will affect the objectivity of the research. The Committee may designate other UNM officials to assist in this process. Examples of conflict of interest management options include:
  - a) Public disclosure of the conflict.
  - b) Monitoring of the research by independent reviewers.
  - c) Modification of the research plan.
  - d) Divestiture of the investigator's conflicting financial interests or placement in a blind trust.
  - e) Escrow of an equity interest until certain triggering conditions are met.
  - f) Prohibition on the investigator's involvement in contract negotiations for the research.
  - g) Severance of the investigator's relationships that create the conflict.
  - h) Disqualification of the investigator from participation in part of the research.
2. All conflicts of interest must be managed to the satisfaction of the Committee for the UNM research 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 cannot be managed, the investigator must withdraw from the research and UNM may need to decline acceptance of the award or terminate the sponsored agreement.

E. Notification of Committee Decisions

1. If the Conflicts of Interest Committee determines that an investigator's disclosure does not constitute a conflict of interest, the Committee will provide written notification of its 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.
2. If the Committee finds that a conflict of interest does exist, the Committee will notify the same individuals, with the addition of the appropriate Dean, of the existence of the conflict and the management plan.
3. The Committee will provide copies of all of its decisions to the Provost and to either the Associate Provost for Research or the Vice President for Health Sciences.

F. Appeals

An investigator may appeal a Committee decision 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. No research expenditures will be made pending appeal.

**VII. REPORTING AND RECORDS REQUIREMENTS**

A. Reports to Research Sponsors

The Conflicts of Interest Committee, ORS and HSC-PAA will work to ensure that UNM complies with the research sponsor's requirements for reporting 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 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.

B. Records Retention

ORS will keep records of all conflict of interest disclosures and all actions taken with respect to those disclosures for at least three years after the later of these events:

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

## VIII. **POLICY ENFORCEMENT**

### A. Types of Noncompliance

Noncompliance with this policy can occur through the following actions:

1. Failure to disclose required information.
2. Failure to follow a conflict of interest management plan.

### B. Enforcement Responsibility

The Provost or designee is responsible for enforcing this policy, including investigating and sanctioning noncompliance. The Conflicts of Interest Committee is responsible for reviewing and managing conflicts of interest referred to it during an enforcement process. The Provost or designee may consult with the Committee during this process.

### C. Reporting Noncompliance

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 or designee. The Committee may likewise report its own concerns about an investigator's noncompliance.
2. UNM encourages good faith reporting of conflict of interest 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.

### D. Investigation

1. The Provost or designee will investigate allegations of policy noncompliance. The procedures in 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.

2. Any information that arises from the investigation that is disclosable under Section V will be referred to the Conflicts of Interest Committee for review and management.

E. Sanctions

The Provost 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.

F. 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.

**IX. APPLICABILITY OF FEDERAL RULES**

If a federal agency issues rules governing conflicts of interest in sponsored UNM 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.

Every investigator is responsible for being familiar with and following the provisions of governing laws and rules related to conflicts of interest.

**X. EFFECTIVE DATE**

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