

MEMORANDUM

TO Michael Doyle PhD; Vice President of Research

Mahyar Amouzegar PhD; President

FROM Sheila O'Sullivan; Policy Analyst and Training Specialist, Research Compliance

Mikell Coleman; Director, Research Compliance

CC Carlos Rey Romero; Associate Vice President of Research

DATE June 11, 2024

SUBJECT Conflicts of Interest in Research Policy

Introduction

New Mexico Tech is now operating under an Interim Conflicts of Interest in Research Policy. This Policy expires on June 11, 2024. This Interim Policy was implemented under the Interim President Daniel López on June 20, 2023.

Please grant your approval to extend this interim policy until [December 9, 2024].

Thank you for your attention and for your review.

Approved: Michael Poule Date:

Approved: A. / A

DocuSigned by:

EBOCE 2025 COAAS

Date: 6/12/2024

6/12/2024



Interim Policy Conflicts of Interest in Research New Mexico Tech Effective Date: June 20, 2023

Last Revised: June 7, 2023 Responsible Office: Office of the Vice President for Research

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Background

The purpose of this policy is to protect the integrity, trust and respect of New Mexico Tech, 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 New Mexico Tech community are engaged in many contractual, consulting and advisory relationships with other universities, government agencies and private sector entities. NMT encourages these relationships for their contributions to research, education, technological advancement and professional development. NMT 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 NMT. Other activities should not interfere or significantly conflict with this responsibility.

Conflicts of interest may occur when an investigator's research responsibilities compete with their 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 NMT 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 Compliance for assistance.

Interim Policy

1. Applicability

1.1. Overall Policy

- 1.1.1. This policy applies to all investigators, including non-NMT investigators. The policy covers actual and potential conflicts of interest associated with participation in NMT research, which includes:
 - 1.1.1.1. Research funded by or through NMT (including outside sponsored funding).
 - 1.1.1.2. Research conducted at NMT, regardless of funding.
 - 1.1.1.3. Non-sponsored research conducted off campus by NMT employees.

1.2. Disclosure Requirements

- 1.2.1. The conflict of interest disclosure requirements applies to all investigators who work on:
 - 1.2.1.1. Sponsored NMT research.
 - 1.2.1.2. Non-sponsored NMT research that is:
 - 1.2.1.2.1. Human subject research;
 - 1.2.1.2.2. Animal subject research; or
 - 1.2.1.2.3. Research funded by a formal award from internal NMT sources based on submission of a proposal.

2. Definitions

2.1. Conflict of Interest

- 2.1.1. Conflict of interest means a situation associated with an investigator's participation in NMT research where it reasonably appears, on an actual or potential basis, that:
 - 2.1.1.1. The investigator's significant financial interest could directly and significantly affect the design, conduct or reporting of NMT research activities; or
 - 2.1.1.2. The investigator's situation could directly and significantly compromise their professional commitments or allegiance to NMT. Examples of the types of situations that may come within this definition include:
 - 2.1.1.2.1. Holding a direct or indirect interest in an outside entity that conducts business in an area closely related to the NMT research or serving as a director, officer, partner, trustee, manager or employee in such an entity.
 - 2.1.1.2.2. Undertaking or steering NMT research to serve the research or other needs of an outside entity, without approval of NMT or the research sponsor.
 - 2.1.1.2.3. Directing potential research efforts away from NMT and toward the investigator's outside entity, or an outside entity in which the investigator has a financial interest.
 - 2.1.1.2.4. 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 NMT or the New Mexico Tech University Research Park Corporation, although these contracts may give rise to conflict of interest situations.
- 2.1.1.2.5. Using privileged information acquired in connection with the investigator's sponsored NMT 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.
- 2.1.1.2.6. Negotiating or influencing the negotiation of contracts related to the investigator's sponsored NMT research between NMT and outside entities with which the investigator has consulting, equity or fiduciary relationships.
- 2.1.1.2.7. Accepting gratuities or special favors from entities with which NMT does or may conduct business in connection with sponsored NMT 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.

2.2. Investigator

2.2.1. 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 NMT 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.

2.3. Non-NMT Investigator

2.3.1. Non-NMT Investigator means any person who is:

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

2.4. Significant Financial Interest

- 2.4.1. Significant financial interest means anything of monetary value belonging to the investigator and their spouse or domestic partner and dependent children, including but not limited to:
 - 2.4.1.1. 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 their spouse, domestic partner, and dependent children.

- 2.4.1.2. 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 their spouse, domestic partner, and dependent children.
- 2.4.1.3. Intellectual property rights, such as patents and copyrights, and royalties from these rights.
- 2.4.2. Significant financial interest does not include the following:
 - 2.4.2.1. Salary, royalties or other remuneration from NMT (including payments or other technology commercialization proceeds through the New Mexico Tech University Research Park Corporation).
 - 2.4.2.2. Income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities.
 - 2.4.2.3. Income from service on advisory committees or review panels for public or nonprofit entities.
 - 2.4.2.4. Interests in widely held investment funds if:
 - 2.4.2.4.1. The investigator does not exercise control over or have the ability to exercise control over the fund's financial interests; and either
 - 2.4.2.4.1.1. The fund is publicly traded or available, or
 - 2.4.2.4.1.2. 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.
 - 2.4.2.4.1.3. Interests in blind trusts if the investigator has no knowledge of the trust assets.

2.5. NMT research

- 2.5.1. NMT Research means a systematic investigation designed to develop or contribute to generalizable knowledge, including basic and applied investigations and product development, that is:
 - 2.5.1.1. Funded by or through NMT (including outside sponsored funding);
 - 2.5.1.2. Conducted at NMT, regardless of funding; or
 - 2.5.1.3. Non-sponsored and conducted off campus by NMT employees.

3. Conflicts of Interest Committee

3.1. Purpose

- 3.1.1. The purpose of the Conflicts of Interest Committee is to protect the integrity of investigators, NMT, and NMT 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.
- 3.1.2. In addition to reviewing conflict of interest disclosures, the Committee may offer advice on general questions concerning conflicts of interest.

3.2. Composition

3.2.1. There will be one Conflicts of Interest Committee formed at the Vice President for Research's discretion. The membership of the committee will be comprised of two (2) faculty members, one (1) person from an applied research center, one (1)

- person not primarily employed by NMT, and one (1) NMT official with administrative responsibility for grants or contracts.
- 3.2.2. Each Committee member will serve a three-year, renewable term. The terms will be staggered to allow for continuity and rotation of members.

3.3. Decision Making

3.3.1. A quorum of three (3) members is required for the 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.

3.4. Disqualification of Committee Members

- 3.4.1. 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:
 - 3.4.1.1. The member is directly involved in the disclosure under review.
 - 3.4.1.2. The member has a prior relationship with the investigator that would interfere with the member's objectivity.
 - 3.4.1.3. The member's objectivity or ability to serve reasonably appears to be adversely affected by the circumstances.

3.5. Removal of Committee members

- 3.5.1. A member will be removed only for good cause and only by the Vice President for Research upon recommendation of a majority of a quorum of the committee. Good cause will include:
 - 3.5.1.1. Change in eligibility status.
 - 3.5.1.2. Insufficient attendance at committee meetings.
- 3.5.2. Committee members may self-recuse at any stage in the review process.
- 3.5.3. 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.
- 3.5.4. 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.

4. Disclosure Requirements

4.1. General

- 4.1.1. The disclosure requirements of this policy apply to all NMT investigators working on:
 - 4.1.1.1. Any sponsored NMT research.
 - 4.1.1.2. Any non-sponsored NMT research that is:
 - 4.1.1.2.1. Human subject research;
 - 4.1.1.2.2. Animal subject research; or
 - 4.1.1.2.3. Research funded by an award from internal NMT sources based on submission of a proposal.

4.2. Sponsored Research Proposals: NMT Investigators

4.2.1. At the time a sponsored research proposal is submitted to Sponsored Projects Administration ("SPA"), all NMT 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:

- 4.2.1.1. Any significant financial interest that would reasonably appear to be affected by the research.
- 4.2.1.2. Any significant financial interest in an entity whose financial interests would reasonably appear to be affected by the research.
- 4.2.1.3. Any other situation that could call into question the investigator's professional commitments in undertaking the research or the investigator's primary allegiance to NMT.
- 4.2.2. 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 SPA. SPA should receive completed disclosure forms from each investigator prior to the proposal's submission to the funding source.
- 4.2.3. The same procedures apply for proposals submitted to SPA 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.

4.3. Sponsored Research Proposals: Non-NMT Investigators

- 4.3.1. For non-NMT investigators who will work on sponsored NMT research, the following conditions must be satisfied when the proposal is submitted to SPA:
 - 4.3.1.1. If the research involves a sub-award with an entity that employs the non-NMT investigator, that entity must provide adequate assurances to NMT 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-NMT investigator must follow the disclosure requirements and procedures specified for NMT investigators.
 - 4.3.1.2. All other non-NMT investigators must follow the disclosure requirements and procedures specified for NMT investigators.

4.4. Non-sponsored Research

- 4.4.1. Each NMT investigator whose NMT research involves human subject research, animal subject research, or research funded by a formal award from internal NMT sources based on submission of a proposal must submit a completed conflict of interest disclosure form to SPA. The disclosure form must be submitted to SPA before the non-sponsored proposal is submitted to the human or animal subject research review committee.
- 4.4.2. Investigators working on other types of non-sponsored NMT research are encouraged to voluntarily submit disclosure forms to SPA, as appropriate.
- 4.4.3. NMT employees working on non-sponsored research at other institutions are encouraged for their self-protection to follow the conflicts of interest procedures of their host institution.

4.5. Ongoing Disclosure Responsibility

4.5.1. Disclosure requirements apply for the duration of the NMT research. Investigators must disclose any of the following, among other things, that occur during the sponsored NMT research:

- 4.5.1.1. A new significant financial interest that would reasonably appear to be affected by the research.
- 4.5.1.2. A new significant financial interest in an entity whose financial interests would reasonably appear to be affected by the research.
- 4.5.1.3. A new situation that could call into question the investigator's professional commitments in undertaking the research or the investigator's primary allegiance to NMT.
- 4.5.1.4. A significant change to a previously reported disclosure.
- 4.5.2. Investigators must submit updated disclosure forms to SPA within 30 days after the disclosable situation arises.
- 4.5.3. All newly-added investigators on NMT research must submit a completed conflict of interest disclosure form to SPA 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.

4.6. Confidentiality of Disclosures

4.6.1. 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.

5. Review and Management of Conflict of Interest Disclosures

5.1. Initial Screening

- 5.1.1. SPA is responsible for initial screening of conflict of interest disclosure forms. SPA 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 NMT sources based on submission of a proposal, SPA will send copies of disclosure forms that indicate a possible conflict of interest to the human or animal subject research review committee, as appropriate.
- 5.1.2. If the referred disclosure form was submitted by an investigator other than the principal investigator, SPA will notify the principal investigator with the general nature of the referral without divulging the particulars of the disclosed information.

5.2. Determination of Conflicts of Interest

5.2.1. The Conflicts of Interest Committee will regularly review and assess conflict of interest disclosure forms referred by SPA. 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 NMT 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.

5.2.2. On occasion, circumstances may require the Vice President for Research or designee to make an expedited decision to accept funding for NMT 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.

5.3. Role of Principal Investigator

- 5.3.1. When the investigator whose disclosure is reviewed by the Conflicts of Interest Committee is not the principal investigator for the NMT 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.
- 5.3.2. 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.
- 5.3.3. 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.

5.4. Management of Conflicts of Interest

- 5.4.1. If the Conflicts of Interest Committee determines that an investigator has a conflict of interest in NMT 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 NMT officials to assist in this process. Examples of conflict of interest management options include:
 - 5.4.1.1. Public disclosure of the conflict.
 - 5.4.1.2. Monitoring of the research by independent reviewers.
 - 5.4.1.3. Modification of the research plan.

- 5.4.1.4. Divestiture of the investigator's conflicting financial interests or placement in a blind trust.
- 5.4.1.5. Escrow of an equity interest until certain triggering conditions are met.
- 5.4.1.6. Prohibition on the investigator's involvement in contract negotiations for the research.
- 5.4.1.7. Severance of the investigator's relationships that create the conflict.
- 5.4.1.8. Disqualification of the investigator from participation in part of the research.
- 5.4.2. All conflicts of interest must be managed to the satisfaction of the Committee for the NMT research to proceed and for funding, if any, to be accepted. This applies to all NMT 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 NMT may need to decline acceptance of the award or terminate the sponsored agreement.
- 5.4.3. Notification of Committee Decisions
 - 5.4.3.1. 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.
 - 5.4.3.2. 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.
 - 5.4.3.3. The Committee will provide copies of all of its decisions to the Vice President for Research.

5.4.4. Appeals

5.4.4.1. An investigator may appeal a Committee decision to the Vice President for Research 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.

5.5. Reporting and Records Requirements

- 5.5.1. Reports to Research Sponsors
 - 5.5.1.1. The Conflicts of Interest Committee and SPA will work to ensure that NMT complies with the research sponsor's requirements for reporting conflicts of interest. As of the date of enactment of this policy, for example, NMT 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. NMT also must report and handle subsequently arising conflicts in PHS-funded research within 60 days after their identification. NMT 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.

5.5.2. Records Retention

- 5.5.2.1. SPA will keep records of all conflict of interest disclosures and all actions taken with respect to those disclosures for at least three (3) years after the later of these events:
 - 5.5.2.1.1. Termination or completion (the date the final expenditures report is submitted) of the NMT research;
 - 5.5.2.1.2. Resolution of any government action involving the records; or
 - 5.5.2.1.3. As otherwise provided by law.

6. Policy Enforcement

6.1. Types of Noncompliance

- 6.1.1. Noncompliance with this policy can occur through the following actions:
 - 6.1.1.1. Failure to disclose required information.
 - 6.1.1.2. Failure to follow a conflict of interest management plan.
- 6.1.2. Enforcement Responsibility
 - 6.1.2.1. The Vice President for Research 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 Vice President for Research or designee may consult with the Committee during this process.

6.2. Reporting Noncompliance

- 6.2.1. 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 Vice President for Research or designee. The Committee may likewise report its own concerns about an investigator's noncompliance.
- 6.2.2. NMT encourages good faith reporting of conflict of interest concerns. NMT 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, NMT does not tolerate bad faith reporting. Reporting an individual in bad faith may result in disciplinary action up to and including dismissal/termination.

6.3. Investigation

- 6.3.1. The Vice President for Research or designee will investigate allegations of policy noncompliance. The procedures in NMT's Research Misconduct Policy may be used for guidance, although investigations under this policy may be handled less formally than specified in the Research Misconduct Policy.
- 6.3.2. 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.

6.4. Sanctions

6.4.1. The Vice President for Research 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.

6.5. Notification of Research Sponsors

6.5.1. If an investigator's noncompliance with this policy may have biased the design, conduct, or reporting of the NMT research, NMT 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 NMT managed conflict of interest, the investigator will be required to disclose the conflict in each public presentation of the research results.

7. Applicability of Federal Rules

- 7.1. If a federal agency issues rules governing conflicts of interest in sponsored NMT 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.
- 7.2. Every investigator is responsible for being familiar with and following the provisions of governing laws and rules related to conflicts of interest.

Interim Policy: Conflict of Interest in Research

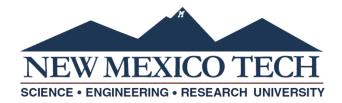
New Mexico Tech Interim Policy Signature and Approval Document		
Legal Review (if applicable)		
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	r. Daniel H López, President, New May be made. Content of this policy o	Mexico Institute of Mining and Technology. cannot be changed.
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Note: Interim Policies

Signature of the President

Interim policies are needed when a policy must be in place and there is not time to follow the procedures outlined in this document. For example, an interim policy might be needed to keep New Mexico Tech in compliance with federal or state laws, or the expectations of an accreditation agency. An interim policy only requires approval by the President. An interim policy must note in its title that it is an interim policy. Such policies are by their nature short-term, and should be replaced by regularly developed and approved policy within one year of their adoption.

Date



New Mexico Institute of Mining and Technology

Conflict Of Interest in Research Procedure

Under Policy: NMT Conflicts of Interest in Research Policy

Version Date: July 26, 2023

Approved by Vice President for Research: Michael Doyle

Procedure Statement and Purpose

The purpose of this procedure is to define the process for identifying, evaluating, managing, and reporting investigators' relationships that have, or may appear to have, an impact on the objectivity and integrity of research conducted at the New Mexico Institute of Mining and Technology (NMT). This procedure applies to research as well as to all sponsored projects. Investigators are required to report:

- 1. professional outside interests annually and at the time of applying for Division of Public Health Services (PHS) funds,
- 2. updates in outside professional and financial interests, and
- 3. research related interests to enable identification of conflicts of interest (COI) in research.

The NMT COI Policy and this procedure are informed by federal regulations, New Mexico law, and ethical practice regarding the identification and management of COI in research and sponsored projects.

Noncompliance with this procedure may result in disciplinary action up to and including termination. NMT supports an environment free from retaliation. Retaliation against anyone who brings forth a good faith concern, asks a clarifying question, or participates in an investigation is prohibited.

Definitions

Conflicts of Interest

Conflicts of interest exist when financial or other professional interests or considerations of the investigator, or members of his or her immediate family, may directly and significantly affect, or have the appearance of directly and significantly affecting, an Investigator's professional judgment in exercising any duty or responsibility to NMT, including the design, conduct or reporting of research. Conflicts of interest in research occur when the investigator, or any member of his/her immediate family, possesses a Significant Financial Interest that is in conflict with his or her NMT responsibilities.

Institutional responsibilities:

"An investigator's professional responsibilities on behalf of the Institution, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as IRBs or Data Safety Monitoring Boards"

Institutional responsibilities for subrecipient investigators only include the work being done for NMT under the subaward. Only financial and professional interests related to those responsibilities must be reported by subrecipient investigators.

Family Members:

Family member definition includes spouse, domestic partner, and/or dependent children. Most research sponsors and the NMT COI in Research Policy use this definition. However, certain federal agencies may have more expansive definitions.

Senior/key personnel:

Senior/key personnel means the project director and/or principal investigator and any other person identified as

Senior/Key Personnel in a grant application or any report submitted to a sponsor by or on behalf of NMT.

Remuneration:

Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Equity Interest:

Any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

FCOI Disclosure Instructions

Overview:

Disclosing the required information at the earliest possible time affords the best protection of an investigator's interests. Investigators are encouraged to disclose any situation that could conceivably be viewed as a conflict of interest or a reportable financial interest. Investigators need to err on the side of caution, so when in doubt, they should disclose. COI disclosure is required for investigators participating in all research proposals, contracts, & protocol submissions to the following offices:

- 1. Sponsored Projects Administration;
- 2. Institutional Review Board (IRB);
- 3. Institutional Animal Care and Use Committee (IACUC); or
- 4. Any NMT unit handling internal research awards using a formal review process.

Who must disclose (Investigator definition):

Disclosure is applicable to all investigators, including faculty, staff, and students. Investigators are defined in the NMT COI in Research Policy, as anyone responsible for a task that could have a significant effect on the design, conduct, or reporting of the research. Any NMT faculty, staff, student, or non-NMT person who is participating in the design, conduct, or reporting of research or a sponsored project that occurs at NMT and who could influence its design, conduct, or reporting shall disclose annually, within 30 days of any material change and, if PHS-supported, shall disclose at the time of applying for PHS support.

What must be disclosed (Significant Financial Interests definition):

Significant Financial Interests include those of the investigator, his or her spouse or domestic partner, and dependent children. Generally, the following financial interest must be disclosed:

Non-NIH Thresholds:

- 1. More than \$10,000 aggregated in a 12 month period from consulting income and salaries other than through NMT;
- 2. More than 5 % or more than \$10,000 equity in a company;
- 3. Intellectual Property rights such as patents, copyrights and royalties other than through NMT or NMT University Research Park Act Corporation ("NMTUPAC");
- 4. Other financial interests of value (honoraria, benefits, gifts, equipment);
- 5. Other significant interests include serving as an entity's: Director, Officer, Partner, Trustee, Manager or Employee; or
- 6. Collaboration with family members.

PHS/NIH Sponsored Project Thresholds:

- 1. Aggregated salary, royalties or other payments, such as consulting fees and honoraria, other than through NMT or NMTUPAC, that total more than \$5,000 in a 12 month period;
- 2. Equity interests in any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the

- value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000;
- 3. Equity interests in any non-publicly traded entity, if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- 4. Intellectual Property rights such as patents, copyrights and royalties other than through NMT or NMTUPAC, upon receipt of income related to such rights and interests;
- 5. Other financial interests of value (honoraria, benefits, gifts, equipment);
- 6. Other significant interests include serving as an entity's: Director, Officer, Partner, Trustee, Manager or Employee;
- 7. Sponsored travel related to an investigator's institutional responsibilities, from an entity that is NOT a federal, state, or local government agency located in the United States, a United States 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 a a United States Institution of higher education; or
- 8. Collaboration with family members.

Investigators supported by PHS agencies are required to show proof of PHS/NIH FCOI training and NMT COI training.

When a disclosure needs to be made:

Disclosures shall be submitted:

- 1. During the first month of the Fall Academic Year;
- 2. Any time before submitting a proposal to PHS agencies; and/or
- 3. Within 30 days after a material change (an acquisition of a significant financial interest or modification to an existing outside interest) to an investigator's previously submitted disclosure.

Required COI Trainings:

The PHS/NIH FCOI Training and the NMT COI Training are required for all research personnel at NMT who are responsible for the design, conduct, or reporting of PHS/NIH research projects. The trainings should be completed prior to applying for PHS/NIH funding.

After completion of the PHS/NIH FCOI and NMT COI trainings, please send a copy of the certificate of completion for each training to coi@nmt.edu. Please also save a copy for your records. These trainings are valid for 4 years and must be renewed thereafter.

NMT investigators that are not funded by PHS may take the PHS or other COI trainings available on the NIH Grants Policy Website at: https://grants.nih.gov/grants/policy/coi/fcoi-training.htm. Regardless of funding, each new research investigator at NMT must complete NMT COI training as part of his/her grants management training prior to beginning research. Non-NMT investigators may take their own institution's COI training.

COI training is to occur at least every four (4) years for PHS-funded investigators and immediately when any of the following occurs:

NMT revises its COI policies and procedures in any manner that affects the requirements of investigators; An investigator is new to NMT; or

NMT finds that an investigator is not in compliance with the COI policy or management plan.

Disclosure Process:

The COI annual disclosure information is collected via an electronic survey program which includes encryption to protect information. A call for annual disclosures is deployed every August. The call for disclosures remains open for 1 month. Upon expiration of the deadline to submit annual disclosures, the Research Compliance Office processes survey information, reviews disclosures and prepares disclosures for COI Committee's consideration. The Committee meets and deliberates. It may request assistance of the investigator, expert witness, or NMT legal counsel at any time in the proceedings.

The electronic survey is also used for submittals of Material Change disclosures and PHS-related transactional disclosures (filled out at the time of applying for PHS funds). Regardless of the type of disclosure, the Research Compliance Office reviews disclosures, collects pertinent information, and organizes for the COI Committee's reviews.

Investigators who have completed the electronic survey but do not disclose COI information which necessitates Committee review are notified that they have fulfilled their annual disclosure obligations and are reminded to disclose any material changes within 30 days of occurrence and to disclose again each time they apply for PHS funding or support.

Investigators who have disclosed interests that give rise to COI may be asked for additional information and will ultimately be notified of the decision on how to reduce, manage, or eliminate their COI.

Reported financial and non-fiscal interests and research relatedness, if relevant, must be up to date at the time of proposal or protocol submission. Continued updates of outside professional interests and research relatedness are required, as appropriate, for the duration of funding of the research or the life of the IRB or IACUC protocol, whichever is longest.

The Research Compliance Office shares information with NMT Sponsored Project Administration and other research compliance offices to ensure these and the above-discussed training requirements are met by individual investigators. In instances where additional information requested to complete the COI review process is not received in a timely manner, those offices will be notified that the investigator's status is non-compliant with NMT COI Policy. Upon receipt of the needed information and completion of the review process, the "compliant" status will be reinstated and notification sent as appropriate.

Public Disclosure:

The COI disclosure information may be subject to public record requests under laws such as FOIA and IPRA. For details whether an entire disclosure or specific portions thereof may be released in response to public record requests, please see NMT Public Record Requests web site: https://www.nmt.edu/foia/ or contact NMT Public Records Custodian at: 575-835-5374 or foi@nmt.edu.

Also, the Research Compliance Office must make available, via a written response to any requestor within five (5) business days of a request of information, any Significant Financial Interest disclosed to the NMT that meets criteria set by Public Health Service regulation applicable for public disclosure:

- The Significant Financial Interest (SFI) was disclosed and is still held by the senior/key personnel;
- COI Committee determines that the SFI is related to the research; and
- COI Committee determines that the SFI is a COI The information, at minimum, to be released is the following:
- the investigator's name;

- the investigator's title and role with respect to the research project;
- the name of the entity in which the SFI is held;
- the nature of the SFI;
- the approximate dollar value of the SFI (permissible ranges are \$0-\$4,999; \$5,000-9,999;
- \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Conflicts of Interest (COI) Committee

The Conflicts of Interest Committee for research is a standing Committee, composed of faculty, administrative personnel, and ex-officio members, as needed, and convened, with an appointed Chair, under the authority of the Vice President for Research. The Committee is charged with: 1) evaluating investigator's Significant Financial Interests and other professional outside interests within the context of specific proposals, research and sponsored projects, and research protocols, 2) determining whether outside interests rise to the level of interests that comprise Conflicts of Interest which could directly and significantly affect, or could appear to affect, the design, conduct, or reporting for the research, 3) developing a resolution, including the recommendation of a management plan, as appropriate, and 4) monitoring compliance.

Outside interests are subject to either expedited or full Committee review, based on amount and type of Financial Interests reported. Committee members are required to adhere to applicable rules of privacy and confidentiality when conducting all COI assessments.

Members of the COI Committee who have financial or non-financial interests in a particular proposal or IRB or IACUC protocol shall recuse themselves from review of said proposal or protocol.

Managing Conflicts of Interest:

If a Conflict of Interest exists, or appears to exist, that would reasonably appear to compromise the objectivity of the research, the Committee develops a plan for reducing, managing or eliminating the conflict, which must be adopted prior to expenditure by NMT of any part of any sponsored research award or contract and before the research begins. The investigator reporting research-related COI may propose a management plan to the Committee for ensuring research objectivity that will be considered (but may not be adopted) by the Committee. Possible management plan components may include, but are not limited to:

- Public disclosure of significant financial interests:
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in the portion of the funded research that would be affected by significant financial interests;
- Divestiture of significant financial interests;
- Severance of relationships that create conflicts; or
- NMT declining the award.

Reporting of and Monitoring the COI Management Plan:

The financial COI's disclosure, determination and/or agreed-upon management plan, if relevant, will be reported to the following, as appropriate:

- The Sponsored Projects Administration office prior to expenditure by NMT of any part of the affected award.
- The IRB or IACUC. The IRB or IACUC may not minimize the management plan developed by the

COI Committee but may require additional safeguards to ensure the optimal protection of research subjects. For example, the IRB may require disclosure in the informed consent form or the IACUC may require additional safeguards to protect the well-being of laboratory animals.

- The Department/Division Chair and/or Dean may be notified and asked to participate in development
 of the management plan, reporting on the management plan, and oversight of the management plan, as
 needed.
- NMT must inform the PHS sponsor (and prime awardee if NMT is the sub-recipient) 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. NMT also must report and manage subsequently arising conflicts in PHS- funded research within 60 days after their identification. NMT is required to report to the National Science Foundation only conflicts of interest that have not been managed prior to expenditure of award funds, and keep the agency informed if a conflict cannot be managed successfully. The Sponsored Projects Administration office reports in accordance with contractual terms or sponsor regulations.
- The PI directing the research will be notified if he or she is not the conflicted individual. At the request of the COI Committee, and as described in the management plan, the investigator must provide an annual, or more frequent, update on the fulfillment of the management plan for review by the Committee. Noncompliance with the agreed-upon management plan shall be referred to the cognizant Chair, Director or Dean. Notification of noncompliance will be made to the IRB, IACUC, and sponsor, as applicable. Sanctions for noncompliance may include removal as an investigator, suspension or termination of the research and/or funding, and termination from employment at NMT.

Appealing a Conflict of Interests Determination:

An investigator may appeal a Committee decision to the Vice President for Research 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.

Enforcement and Investigations:

Under the NMT COI in Research Policy, the Vice President for Research or designee is charged with enforcement and investigatory responsibilities. If a research investigator fails to comply with this Policy, they may be suspended from all relevant activities until the matter is resolved or other appropriate action is implemented. The sponsoring agency and other research partners may need to be notified of the fact that an investigation has been commenced and, ultimately, the investigation conclusion and findings.

Regardless of funding or its source, failure to comply with the NMT COI in Research Policy or with a determination under it, will be brought to the attention of the investigator's supervisor and Dean. Depending upon the egregiousness of the alleged noncompliance, the Vice President for Research may implement corrective action(s) including, but not limited to, suspension from proposal submittal until the matter is resolved, withdrawal of pending proposals, and/or placing a hold on or terminating an active award, contract, or cooperative agreement. In addition, NMT has reporting obligations to the sponsor about any determinations and findings that an Investigator has failed to comply with the NMT COI in Research Policy.

Retrospective review.

In situations where a COI was not identified or managed in a timely manner, including but not limited to an investigator's failure to disclose relevant information, or an investigator's failure to materially comply with a management plan, the Committee will complete a retrospective review of the Investigator's activities and the

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research project. If the Committee determines that research conducted during the period of non-compliance has been biased, the funding agency will be notified and a management plan may be implemented going forward, or suspension of research activities/ expenditures may occur. If bias by the investigator is found, the report will include a mitigation report in accordance with the applicable regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

Records Retention:

Records of conflict of interest disclosures and all actions taken with respect to those disclosures shall be kept for at least three years after the later of these events:

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

Contacts:

The Office of the Vice President for Research officially interprets the NMT COI in Research Policy. The Office of the Vice President for Research is responsible for obtaining approval for any revisions to it as required by the policy *Creating and Maintaining Policies and Procedures* through the appropriate governance structures. Compliance with NMT COI in Research Policy is the responsibility of the Vice President for Research or designee.