

# **CONFLICT OF INTEREST IN RESEARCH PROCEDURES**

Procedures for Implementation of Conflicts of Interest in Research Policy  
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## A. Procedure Statement and Purpose

This procedure document accompanies and implements the NMT Conflicts of Interest in research Policy. [link] 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:

- professional outside interests annually and at the time of applying for sponsored research funds,
- updates in outside professional and financial interests, and
- 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.

## B. Conflicts of Interest Defined

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:

1. The investigator's significant financial interest could directly and significantly affect the design, conduct or reporting of NMT research activities; or
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. 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.
  - 2.2. Undertaking or steering NMT research to serve the research or other needs of an outside entity, without approval of NMT or the research sponsor.
  - 2.3. 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.
  - 2.4. 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.

- 2.5. 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.
- 2.6. 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.
- 2.7. 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.

## C. Significant Financial Interest Thresholds

The following thresholds apply to financial conflicts of interest for all NMT Research, and must be reported during required disclosure.

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
  - 1.1. With regard to any (domestic or foreign) 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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  - 1.2. With regard to any non-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, 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); or
  - 1.3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a United States Federal, state, or local government agency, an Institution of higher education located within the United States 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. The Institution's COI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the

Institution's COI policy and procedures, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an COI with the NMT research.

3. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by 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 United States Institution of higher; or income from service on advisory committees or review panels for 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 United States Institution of higher education.

## D. Disclosure Requirements

### Applicability

The disclosure requirements of the Conflicts of Interest in Research policy apply to all NMT investigators working on

- Any sponsored NMT research.
  - Any non-sponsored NMT research that is:
    - Human subject research;
    - Animal subject research; or
    - Research funded by an award from internal NMT sources based on the submission of a proposal.
1. Disclosure during the annual disclosure window:
    - 1.1. All investigators will complete an electronic COI disclosure form during the specified disclosure period, managed by the Office of Research. The disclosure form includes questions about
      - 1.1.1. Financial conflicts of interest, and
      - 1.1.2. Any situation that could call into question the investigator's professional commitments in undertaking the research or the investigator's primary allegiance to NMT (see B.2.).
  2. Disclosure for a new proposal or a significant change:
    - 2.1. All investigators will complete an electronic COI disclosure form, provided by and managed by the Office of Research.
    - 2.2. Disclosure forms outside the annual disclosure window will be made by using the link to the electronic form.
  3. Sponsored Research Proposals - NMT Investigators

At the time a new sponsored research proposal is submitted to the Office of Research and/or Sponsored Projects Administration, all NMT individuals who will serve as investigators on the proposed research must concurrently submit a completed conflict of interest disclosure (see D.2.2. above), or have done so during the disclosure window the previous fall semester (see D.2.1. above).

- 3.1. The principal investigator, and any co-principal investigator, are responsible for identifying the research investigators, informing them of the requirements of this procedure and providing a list of their names to the Office of Research. The Office of Research should receive completed disclosure forms from each investigator prior to the proposal's submission to the funding source.
4. Proposals submitted to the Office of Research 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.
5. Sponsored Research Proposals - Non-NMT Investigators  
For non-NMT investigators who will work on sponsored NMT research, the following conditions must be satisfied when the proposal is submitted to the Office of Research:
  - 5.1. 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.
  - 5.2. All other non-NMT investigators must follow the disclosure requirements and procedures specified for NMT investigators.
6. Non-sponsored Research
  - 6.1. 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 the Office of Research.
  - 6.2. Investigators working on other types of non-sponsored NMT research are encouraged to voluntarily submit disclosure forms to the Office of Research, as appropriate.
  - 6.3. 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.
7. Ongoing Disclosure Responsibility
  - 7.1. 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:
    - 7.1.1. A new significant financial interest that would reasonably appear to be affected by the research.
    - 7.1.2. A new significant financial interest in an entity whose financial interests would reasonably appear to be affected by the research.
    - 7.1.3. 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.

- 7.1.4. A significant change to a previously reported disclosure.
- 7.2. Investigators must submit updated disclosure forms to the Office of Research within 30 days after the disclosable situation arises.
- 7.3. All newly-added investigators on NMT research must submit a completed conflict of interest disclosure form to the Office of Research 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.
8. 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.

## E. Conflicts of Interest Committee

1. Purpose  
The charge of the Conflicts of Interest Committee is to protect the integrity of investigations, 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. In addition to reviewing conflict of interest disclosures, the Committee may offer advice on general questions concerning conflicts of interest.
2. Composition  
There will be one (1) 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 a research center, one (1) person not primarily employed by NMT, and one (1) NMT official with administrative responsibility for grants or contracts. Committee members elect a Chair who is an NMT employee. The Committee is supported by the Research Compliance COI administrator, who schedules and facilitates the meetings, but has no voting rights.
3. Decision Making  
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.
4. Terms  
Each Committee member will serve a two-year, renewable term. The terms will be staggered for all for continuity and rotation of members.
5. Disqualification of Committee Members  
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. A committee member may abstain from reviewing a disclosure if they feel they cannot be impartial.
6. Removal of Committee Members

A member may be removed for cause by the Vice President for Research upon recommendation of a majority of a quorum of the committee. Reasons for removal include failure to follow the COI policy and procedures, disclosing confidential information, or violation of other university policies and procedures.

## F. Review and Management of Conflict of Interest Disclosures

1. Initial Screening
  - 1.1. All disclosures will be reviewed by the Research Compliance COI administrator.
  - 1.2. Any disclosures with a potential COI will be forwarded to the Conflicts of Interest Committee.
  - 1.3. The COI Committee will review the disclosures sent to them, determine whether a COI exists, and if no conflict of interest exists, it will conclude its assessment. If their assessment is inconclusive, the committee 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.
  - 1.4. If the Committee does find there is a conflict of interest, they will work with the investigator to determine how it might be managed or resolved to best protect the investigator, the institution, and the research results. They will then devise a management plan together with the Investigator
2. Determination of Conflicts of Interest
  - 2.1. The Conflicts of Interest Committee will regularly review and assess conflict of interest disclosure forms. 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.
  - 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.
3. Role of Principal Investigator
  - 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 determines 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.

- 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.
- 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 the involvement of the principal investigator in managing the conflict or withdraw from the research.

#### 4. Managing Conflicts of Interest

- 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. Key elements of a management plan include.
  - 4.1.1. Role and principal duties of the conflicted Investigator in the research project;
  - 4.1.2. Conditions of the management plan;
  - 4.1.3. How the management plan is designed to safeguard objectivity in the research project;
  - 4.1.4. Confirmation of the Investigator's agreement to the management plan;
  - 4.1.5. How the management plan will be monitored to ensure Investigator compliance; and
  - 4.1.6. Other information as needed.
- 4.2. Examples of conflict of interest management options include:
  - 4.2.1. Public disclosure of the conflict.
  - 4.2.2. Monitoring of the research by independent reviewers.
  - 4.2.3. Modification of the research plan.
  - 4.2.4. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - 4.2.5. Divestiture of the investigator's conflicting financial interests or placement in a blind trust.
  - 4.2.6. Escrow of an equity interest until certain triggering conditions are met.

- 4.2.7. Prohibition on the investigator's involvement in contract negotiations for the research.
- 4.2.8. Severance of the investigator's relationships that create the conflict.
- 4.2.9. Disqualification of the investigator from participation in part of the research.
- 4.3. 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.
  - 4.3.1. After a management plan is agreed on, the Committee will appoint a plan manager for the management plan, and implement that plan. The plan will be in place as long as the investigator participates in the project, or until the project has been completed. Details of the COI and the management plan in place to mitigate it shall be sent to the funding agency.
  - 4.3.2. The management plan shall be reviewed annually for sufficiency and efficacy. If necessary, it shall be revised to meet evolving requirements.
- 4.4. Notification of Committee Decisions
  - 4.4.1. 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.
  - 4.4.2. If the Committee finds that a conflict of interest does exist, the Committee will notify the investigator, the COI administrator, and any individuals required to participate in the management plan of the existence of the conflict and the management plan.
  - 4.4.3. The Committee will provide copies of all of its decisions to the Vice President for Research.
- 5. Appeals
  - 5.1.1. 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.
- 6. Reporting and Records Requirements
  - 6.1. Reports to Research Sponsors
    - 6.1.1. The Conflicts of Interest Committee and the Office of Research will work to ensure that NMT complies with the research sponsor's requirements for reporting conflicts of interest. 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.

#### 6.1.2. Records Retention

- 6.1.2.1. The Office of Research 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:
- 6.1.2.2. Termination or completion (the date the final expenditures report is submitted) of the NMT research;
- 6.1.2.3. Resolution of any government action involving the records; or
- 6.1.2.4. As otherwise provided by law.

### 7. Policy Enforcement

#### 7.1. Types of Noncompliance

- 7.1.1. Noncompliance with these policy implementing procedures or the COI in Research policy can occur through the following actions: 6.1.1.1. Failure to disclose required information.

- 7.1.1.1. Failure to follow a conflict of interest management plan.

#### 7.1.2. Enforcement Responsibility

- 7.1.3. 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.

#### 7.2. Reporting Noncompliance

- 7.2.1. 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.
- 7.2.2. 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.

#### 7.3. Investigation

- 7.3.1. 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.
- 7.3.2. 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.

#### 7.4. Sanctions

7.4.1. 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.

7.5. Notification of Research Sponsors

7.5.1. 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.

8. Applicability of Federal Rules

- 8.1. 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 federal agencies such as the Department of Energy, National Science Foundation, and Public Health Service 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.
- 8.2. Every investigator is responsible for being familiar with and following the provisions of governing laws and rules related to conflicts of interest.

# COI Procedures Implementing OR-1.1








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