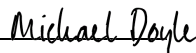


New Mexico Institute of Mining and Technology
 Conflicts of Interest in Research Procedure
 Under Policy: NMT Conflicts of Interest in Research Policy
 Version Date: August 2, 2023
 Approved by Vice President for Research:

DocuSigned by:

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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.

Investigator

The PD/PI and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of NIH-funded research, or proposed for such funding, and which may include for example, collaborators or consultants. Includes investigators who plan to participate in or who participate in NIH-funded research.

Significant Financial Interest

See FCOI disclosure instructions.

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 is responsible for the design, conduct, or reporting of PHS-funded research shall disclose annually, within 30 days of discovering or acquiring a new SFI 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

Significant Financial Interests definition for PHS/NIH Sponsored Projects:

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:
 - (i) With regard to 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. 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:
 - (ii) 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
 - (iii) 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 FCOI 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 FCOI policy, 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 FCOI with the PHS-funded 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.

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

Additional disclosure required for all NMT investigators:

1. Collaboration with family members.

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 must be completed prior to engaging in PHS/NIH funded research.

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, (i.e., upon discovering or acquiring a new SFI), 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 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, (e.g., disclose in publications, presentations, to research personnel working on the study, to human subjects research participants);
- 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 research project. The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

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.