

New Mexico Tech
Financial Conflict of Interest Policy for DHHS Funded Research
Enacted: 11 December 2012

I. Background

The United States Department of Health and Human Services has issued revised regulations pertaining to financial conflicts of interest. The regulations require that all individuals who participate in the design, conduct, or reporting of research funded by the Public Health Service complete training on financial conflicts and disclose personal financial interests that could give rise to an actual conflict of interest or the appearance of a conflict. A copy of the full text of the regulations and the final rule implementing the regulations published in the Federal Register can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.

All NEW MEXICO TECH (NMT) research professionals, including full-time, part-time, and adjunct staff, will be required to complete training provided by NMT (In process), and National Institutes of Health (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>), submit a financial conflict of interest screening form, and disclose relevant Financial Interests if they worked on a PHS-funded project in the preceding year, if they expect to work on a PHS-funded project in the upcoming year, or at any time they are named in a proposal for a PHS-funded project. Key members of management and certain administrative and support department staff also will be required to complete the training and the screening form and provide relevant disclosures.

The PHS financial conflict of interest disclosure requirement is entirely consistent with NMT's corporate values and Institutional Principles, including objectivity in our work and our commitment to avoid actual or apparent conflicts of interest. The requirements of this Policy should be read in conjunction with NMT's Conflict of Interest Policy, which provides general instruction on preventing, recognizing, and mitigating conflicts of interest.

II. Definitions

- A.** Disclosure means an Investigator's disclosure of significant Financial Interests to NMT.
- B.** Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- C.** Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.
- D.** Healthcare-Related Entities include any organization or entity (including both publicly traded and private companies) that provides healthcare-related products or services, including but not limited to:
 - 1. Healthcare providers, including hospitals and clinics
 - 2. Healthcare insurance companies
 - 3. Healthcare research or service organizations
 - 4. Health information technology companies
 - 5. Medical device and equipment manufacturers and distributors
 - 6. Medical technology companies
 - 7. Pharmaceutical companies
 - 8. Other organizations that could be impacted by healthcare-related research, including alcohol, tobacco, or food products companies
 - 9. Any other entity, publicly-traded or private, that could be materially affected by the conduct or results of PHS-funded Research
- E.** Institutional Responsibilities means an Investigator's professional responsibilities relating to seeking (by submission of proposals for the award of contracts or grants) or conducting PHS-funded Research, including but not limited to: research; peer review; editing, publication, and dissemination of research; service on the NMT Institutional Review Board; and relevant work performed in administrative or support functions including the Office of the General Counsel, the Office of External Affairs, the Office of the Chief Financial Officer, and the Office of Services.
- F.** Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. For purposes of this policy, this includes the following at New Mexico Tech:
 - 1. All research professionals (including all research titles)
 - 2. Research Assistants

3. Project Associates
4. Survey Research Group
5. Peer reviewers
6. Research Programmers
7. Graduate students
8. Communications Analysts
9. Human Subjects Protection Committee members
10. Key members of the administrative staff, including the Operations Group and other senior administrative staff; Office of External Affairs staff responsible for the editing, publication, or dissemination of NMT Research; and management and professional staff in the Office of the General Counsel, Office of the Chief Financial Officer, and the Office of Services

G. Managing an FCOI means taking action to address an FCOI, which can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct, and reporting of Research will be free from bias.

H. PHS means the Public Health Service of the United States Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health. The PHS includes the agencies listed below:

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of the Assistant Secretary for Health (OASH)
9. Office of the Assistant Secretary for Preparedness & Response (ASPR)
10. Office of Global Affairs (OGA)
11. Substance Abuse and Mental Health Services Administration (SAMHSA)

In addition to the PHS agencies listed above, NMT Investigators responsible for the design, conduct, or reporting of research funded by the Centers for Medicare and Medicaid Services (CMS) also must comply with this policy.

I. Research means a systematic investigation, study, or experiment designed to develop or contribute to the general knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from PHS.

J. Significant Financial Interest (SFI) means:

“Significant” means that the Financial Interest would have a material effect on the Research. A Significant Financial Interest means a Financial Interest in any Healthcare-Related Entity consisting of one or more of the following interests of the Investigator, and of the Investigator's spouse or domestic partner, dependent child, or other member of the Investigator's household, if : (i) the financial interest reasonably appears to be related to the Investigator's Institutional Responsibilities at NMT, and (ii) the aggregate value of all interests held in a particular Healthcare-Related Entity exceeds \$5,000:

1. Remuneration (including salary, wages, consulting fees, honoraria, and any other fee for services)
2. Defined benefit pension payments or other post-employment payments
3. Service in a management position such as a board member, director, officer, partner, or trustee of a Healthcare-Related Entity
4. Ownership of an equity interest (including stock, stock options, bonds, or any other ownership interest)
5. Holdings in a healthcare sector-oriented mutual fund
6. Intellectual property rights (e.g., patents or copyrights) from which income is received
7. Reimbursed or sponsored travel related to an Investigator's Institutional Responsibilities
 - a. Sponsored travel means travel expenses paid on behalf of an Investigator (or relevant family member) rather than paid by reimbursement
 - b. Travel reimbursed or sponsored by the following is excluded: federal, state, or local government agencies; institutions of higher education; academic teaching hospitals; medical centers; and research institutes affiliated with institutions of higher education.

- c. Investigators will be required to provide the following information with respect to any reimbursed or sponsored travel: name of entity that sponsored or reimbursed any expenses associated with the trip; purpose of the trip; destination; date and duration of the trip; and amount of reimbursement received
8. SFIs do **not include**:
- a. Salary, wages, and remuneration paid by New Mexico Tech
 - b. Travel expenses paid or reimbursed by NMT
 - c. Income from mutual funds and retirement accounts (other than healthcare sector-oriented funds, see paragraph J.2.e, above), as long as the Investigator does not directly control the investment decisions made by the funds
 - d. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education
 - e. Service on advisory committees or review panels for a federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education

III. Financial Reporting Requirements

All full- and part-time NMT Investigators and all adjunct and affiliated adjunct staff must complete a screening form and disclose all Financial Interests relating to Research funded by PHS and complete the related training provided by NMT. The Financial Interest screening and disclosure form is available here. All Investigators must fully and accurately complete the form within the time allotted depending on the circumstances giving rise to the need for disclosure. Failure to accurately and timely complete the training and the form and to provide updates as required by this policy could result in disciplinary action, up to and including termination.

Investigators named in a proposal for a PHS-funded project on or after August 24, 2012 must complete the training and the screening and disclosure form before the proposal is submitted. Investigators who participate in the design, conduct, or reporting of PHS-funded work awarded on or after August 24, 2012 also must complete the training and the form before beginning any work on the project, whether or not they were named in the proposal.

All Investigators must update the disclosure form at least annually **and within 30 days of receiving, acquiring, or discovering either a new Financial Interest or additional interests from an entity previously disclosed by the Investigator**. All employees covered by the PHS regulations are expected to recognize their continuing obligation to timely disclose relevant Financial Interests to ensure TECH's compliance with the reporting and certification requirements of the PHS regulations.

IV. Review and Evaluation of Financial Interests Disclosed by Investigators

A disclosure of a Financial Interest does not, by itself, create an impermissible conflict of interest. Each Financial Interest disclosure will be reviewed by the Office of the General Counsel. The Vice President, General Counsel is responsible for determining when an actual or potential conflict of interest exists in a given situation — that is, when a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research — and for taking action as necessary to Manage such conflicts of interest, including development and implementation of a management plan. This responsibility will be exercised in cooperation with the relevant unit or corporate manager and with full participation by the employee. A variety of criteria may be considered in determining whether a particular Financial Interest creates a conflict of interest with respect to a particular PHS-funded project.

THE UNIVERSITY will take appropriate steps to Manage FCOI to ensure that ITS's research is free of bias or the appearance of bias. As described in the PHS regulations, some examples of how financial conflicts of interest may be addressed and Managed include:

1. Public disclosure of an Investigator's Significant Financial Interests; disclosures will only occur after notice to and consultation with the Investigator
2. Disclosure of FCOI directly to participants in Research projects involving human subjects;
3. Monitoring of Research projects by reviewers who do not have FCOI and who are capable of implementing measures to protect the design, conduct, or reporting of the Research against bias arising from identified FCOI
4. Modification of the research plan, including, for example, change of personnel or personnel responsibilities with respect to particular tasks

5. Disqualification of personnel from participation in all or a portion of a Research project funded by PHS
6. Reduction or elimination of a Significant Financial Interest (e.g., sale of stock)
7. Severance of relationships (e.g., consulting activities) that create actual or potential conflicts

V. NEW MEXICO TECH's Responsibilities

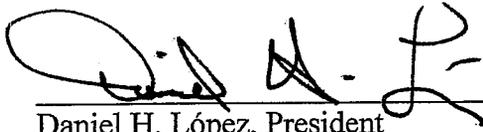
NEW MEXICO TECH will take reasonable steps to ensure that its subcontractors comply with the Department of Health and Human Services Financial Conflict of Interest regulations.

NEW MEXICO TECH will comply with regulatory requirements relating to our institutional responsibilities, including certification of compliance, maintenance of records, responses to requests for information, and reporting requirements.



NEW MEXICO TECH
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OFFICE OF THE PRESIDENT

On behalf of New Mexico Tech, I have approved the regulations regarding Conflict of Interest as defined by Department of Health and Human Services Financial Conflict of Interest regulations. New Mexico Tech will comply with its institutional responsibilities.



Daniel H. López, President

focused education in science and engineering

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